



US009186184B2

(12) **United States Patent**
Janowski

(10) **Patent No.:** **US 9,186,184 B2**
(45) **Date of Patent:** **Nov. 17, 2015**

(54) **SPINAL FIXATION SYSTEM AND METHOD**

(75) Inventor: **Brian P. Janowski**, Marquette, MI (US)

(73) Assignee: **PIONEER SURGICAL TECHNOLOGY, INC.**, Marquette, MI (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/366,117**

(22) Filed: **Feb. 3, 2012**

(65) **Prior Publication Data**

US 2012/0209332 A1 Aug. 16, 2012

Related U.S. Application Data

(60) Provisional application No. 61/442,617, filed on Feb. 14, 2011.

(51) **Int. Cl.**
A61B 17/70 (2006.01)
A61B 19/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 17/7038** (2013.01); **A61B 17/7041** (2013.01); **A61B 17/7082** (2013.01); **A61B 17/7085** (2013.01); **A61B 2019/307** (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/7041; A61B 17/7076; A61B 17/7037; A61B 17/7035; A61B 17/7083; A61B 17/8083
USPC 606/86 A, 99, 264-279
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,653,481 A * 3/1987 Howland et al. 606/261
5,030,220 A * 7/1991 Howland 606/261
5,584,831 A * 12/1996 McKay 606/86 A

5,725,528 A * 3/1998 Errico et al. 606/266
5,733,285 A * 3/1998 Errico et al. 606/278
5,735,851 A * 4/1998 Errico et al. 606/266

(Continued)

FOREIGN PATENT DOCUMENTS

BR 0600528-4 10/2007
EP 1638472 11/2012

(Continued)

OTHER PUBLICATIONS

Website, Medicea, Products, Thoraco-Lumbar fusion, <http://www.Medicea.com/version-US/produit-thoracolumbar-fixation.php?Ig=us&rub=18partie=3&55partie=0>, accessed Jan. 17, 2012, 3 pages.

(Continued)

Primary Examiner — Eduardo C Robert

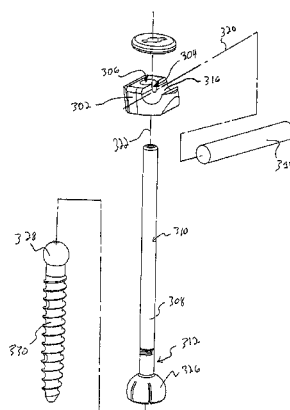
Assistant Examiner — Jacqueline Johanas

(74) *Attorney, Agent, or Firm* — Fitch, Even, Tabin & Flannery LLP

(57) **ABSTRACT**

A spinal fixation system is provided that, in one form, comprises a pedicle screw assembly having a coupling device with an elongate member for guiding a fixation element, such as a spinal rod, into the coupling device and a lock device for fixing the spinal rod to the coupling device. The pedicle screw assembly may be passed through a small incision and connected to a vertebral bone. By connecting a second pedicle screw assembly to a second vertebral bone, the elongate members of the pedicle screw assemblies provide guideposts for directing the spinal rod subcutaneously between the pedicle screw assemblies and into the coupling devices thereof.

14 Claims, 29 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

- 5,800,435 A * 9/1998 Errico et al. 606/261
6,050,997 A 4/2000 Mullane
6,123,706 A * 9/2000 Lange 606/264
6,248,104 B1 * 6/2001 Chopin et al. 606/267
6,254,602 B1 * 7/2001 Justis 606/272
6,267,765 B1 * 7/2001 Taylor et al. 606/86 A
6,371,957 B1 * 4/2002 Amrein et al. 606/272
6,554,831 B1 * 4/2003 Rivard et al. 606/253
6,786,907 B2 * 9/2004 Lange 606/250
6,887,242 B2 * 5/2005 Doubler et al. 606/274
7,163,539 B2 1/2007 Abdelgany et al.
7,166,108 B2 * 1/2007 Mazda et al. 606/305
7,344,537 B1 * 3/2008 Mueller 606/278
7,731,734 B2 * 6/2010 Clement et al. 606/246
7,753,939 B2 * 7/2010 Ritland 606/264
7,763,057 B2 7/2010 Abdelgany et al.
7,789,897 B2 * 9/2010 Sanders 606/278
7,846,093 B2 * 12/2010 Gorek et al. 600/206
8,021,396 B2 * 9/2011 Winslow et al. 606/264
8,043,343 B2 * 10/2011 Miller et al. 606/279
8,057,518 B2 * 11/2011 Frasier et al. 606/267
8,083,773 B2 * 12/2011 Durrani 606/259
8,162,990 B2 * 4/2012 Potash et al. 606/266
8,221,457 B2 * 7/2012 Delecric et al. 606/246
8,221,470 B2 * 7/2012 Kumar et al. 606/265
8,226,656 B2 * 7/2012 McBride 606/86 A
8,246,623 B2 * 8/2012 Peultier et al. 606/86 A
8,308,772 B2 11/2012 Clement et al.
8,308,775 B2 11/2012 Clement et al.
8,333,770 B2 * 12/2012 Hua 606/86 A
8,470,001 B2 * 6/2013 Trautwein et al. 606/264
8,617,216 B2 * 12/2013 Brumfield 606/266
8,894,690 B2 * 11/2014 Ludwig et al. 606/264
2002/0169450 A1 * 11/2002 Lange 606/61
2003/0023240 A1 * 1/2003 Amrein et al. 606/61
2003/0028191 A1 * 2/2003 Shluzas 606/61
2003/0045874 A1 * 3/2003 Thomas, Jr. 606/61
2003/0073996 A1 * 4/2003 Doubler et al. 606/61
2003/0093078 A1 * 5/2003 Ritland 606/73
2004/0064140 A1 4/2004 Taylor et al.
2004/0254577 A1 * 12/2004 Delecric et al. 606/61
2005/0010215 A1 * 1/2005 Delecric et al. 606/61
2005/0096654 A1 * 5/2005 Lin 606/61
2005/0171537 A1 * 8/2005 Mazel et al. 606/61
2005/0192571 A1 9/2005 Abdelgany
2005/0192572 A1 9/2005 Abdelgany et al.
2005/0192579 A1 * 9/2005 Jackson 606/72
2005/0228382 A1 * 10/2005 Richelsoph et al. 606/61
2006/0079892 A1 * 4/2006 Roychowdhury et al. 606/61
2006/0079899 A1 * 4/2006 Ritland 606/61
2006/0083603 A1 * 4/2006 Jackson 411/386
2006/0111712 A1 * 5/2006 Jackson 606/61
2006/0167455 A1 7/2006 Clement et al.
2006/0184178 A1 * 8/2006 Jackson 606/99
2006/0229606 A1 10/2006 Clement et al.
2007/0016190 A1 1/2007 Martinez et al.
2007/0032162 A1 * 2/2007 Jackson 446/1
2007/0072493 A1 3/2007 Sournac et al.
2007/0078460 A1 * 4/2007 Frigg et al. 606/61
2007/0093831 A1 4/2007 Abdelgany et al.
2007/0093832 A1 4/2007 Abdelgany
2007/0100339 A1 5/2007 Clement et al.
2007/0106123 A1 * 5/2007 Gorek et al. 600/210
2007/0149973 A1 6/2007 Clement et al.
2007/0233066 A1 * 10/2007 Rezach 606/61
2007/0270810 A1 * 11/2007 Sanders 606/61
2008/0091213 A1 * 4/2008 Jackson 606/99
2008/0312696 A1 * 12/2008 Butters et al. 606/264
2009/0030457 A1 1/2009 Janowski et al.
2009/0062864 A1 * 3/2009 Ludwig et al. 606/301
2009/0222044 A1 * 9/2009 Gorek 606/279
2009/0222045 A1 * 9/2009 Gorek 606/279
2009/0270916 A1 * 10/2009 Ramsay et al. 606/246
2010/0168796 A1 * 7/2010 Eliassen et al. 606/264
2010/0241172 A1 * 9/2010 Biyani et al. 606/279
2010/0249798 A1 9/2010 Sournac et al.
2010/0292739 A1 * 11/2010 Schwab 606/305
2011/0015679 A1 1/2011 Fiere et al.
2011/0112581 A1 5/2011 Clement
2011/0245877 A1 * 10/2011 Pisharodi 606/268
2011/0282400 A1 * 11/2011 Jackson 606/305
2013/0072991 A1 * 3/2013 Rathbun 606/305

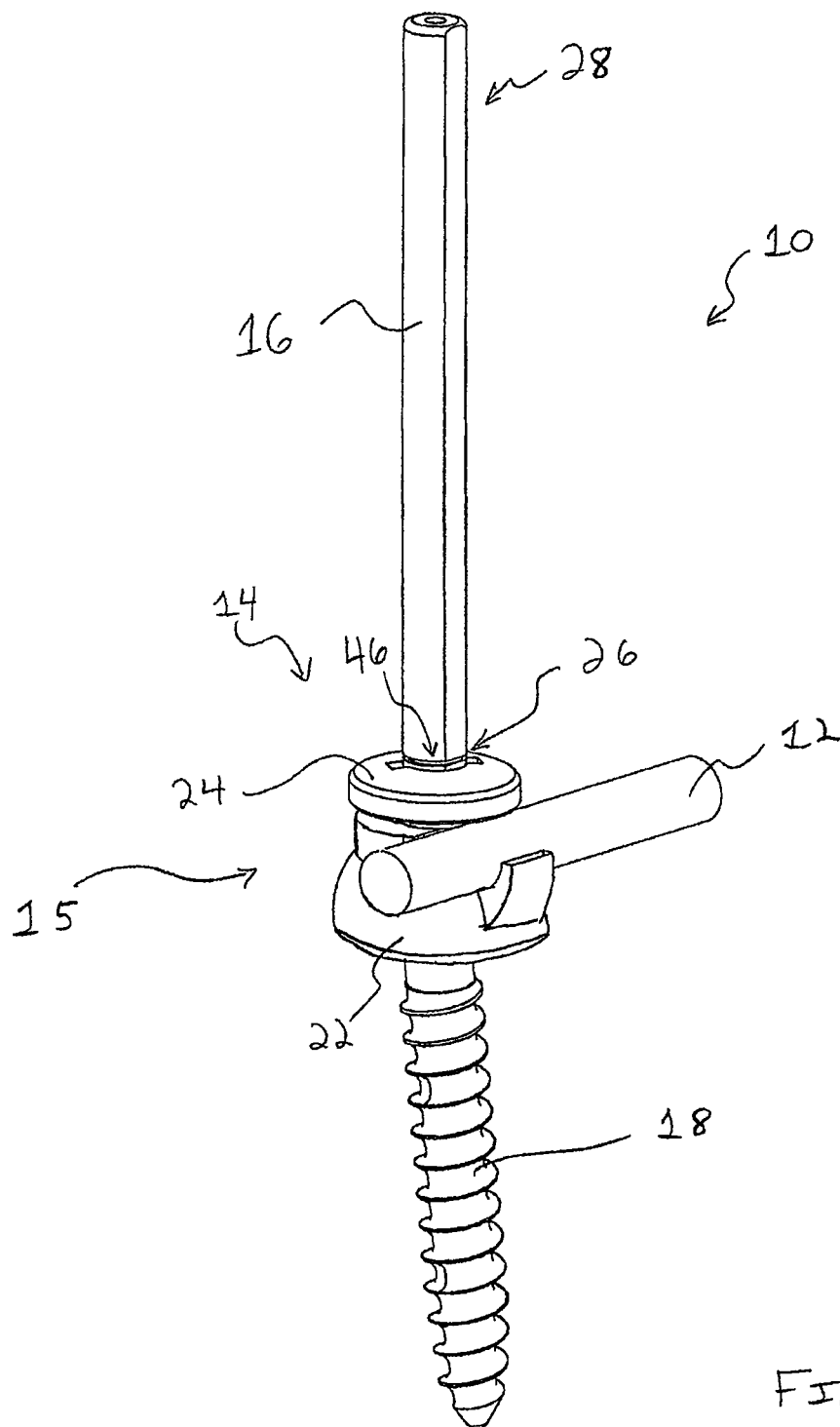
FOREIGN PATENT DOCUMENTS

EP	2445427	3/2013
FR	2956803	9/2002
FR	2867375	9/2005
WO	2005000136	1/2005
WO	2009011929	1/2009
WO	2010150140	12/2010
WO	2012029025	3/2012
WO	2013014589	1/2013

OTHER PUBLICATIONS

Website, YouTube, PASS MIS Technique 4 Level Trauma, <http://www.youtube.com/watch?v=ofm3w0qy6hw>, accessed Jan. 27, 2012, 2 pages, only 2 pages of screen shot considered, content of video not considered /J.J./ Oct. 9, 2013.

* cited by examiner



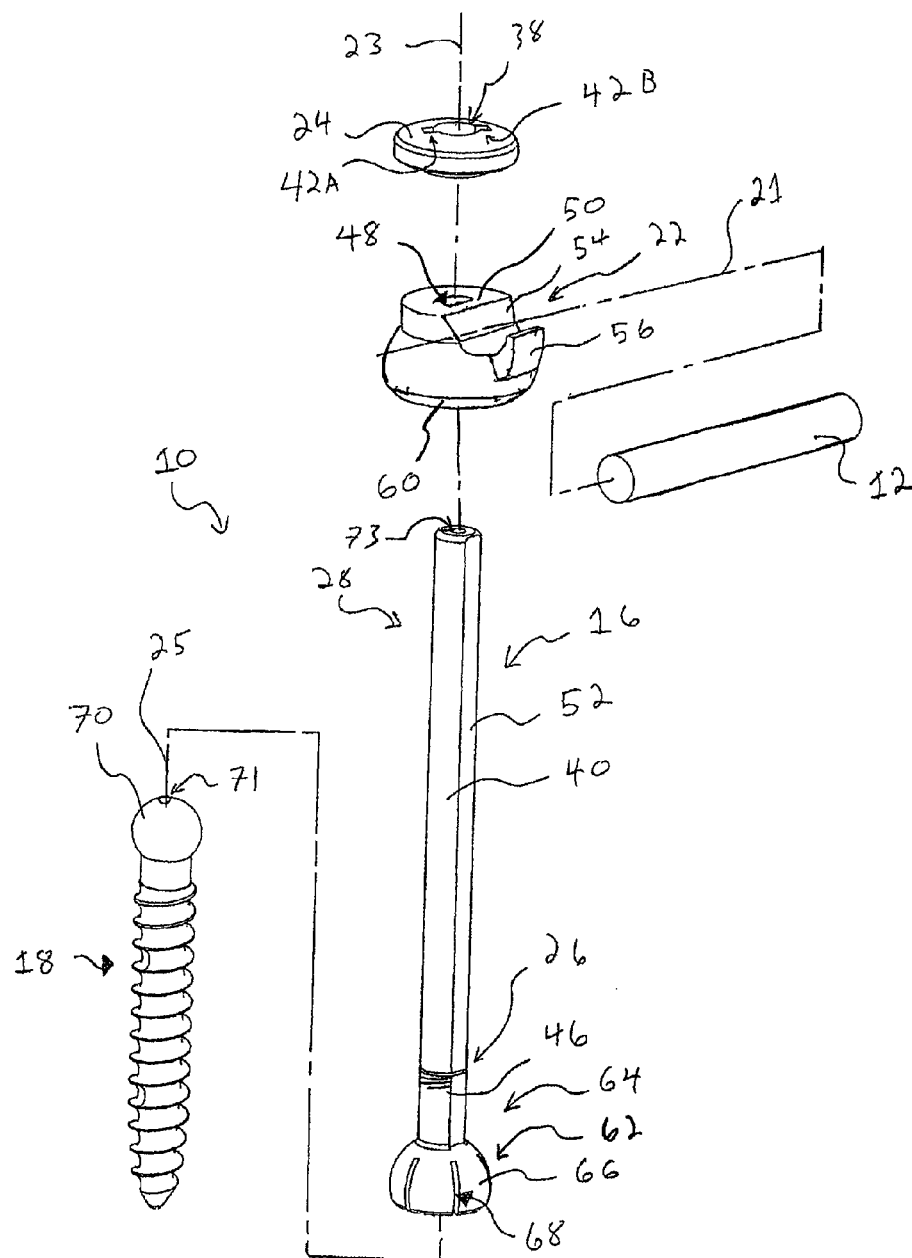


FIG. 2A

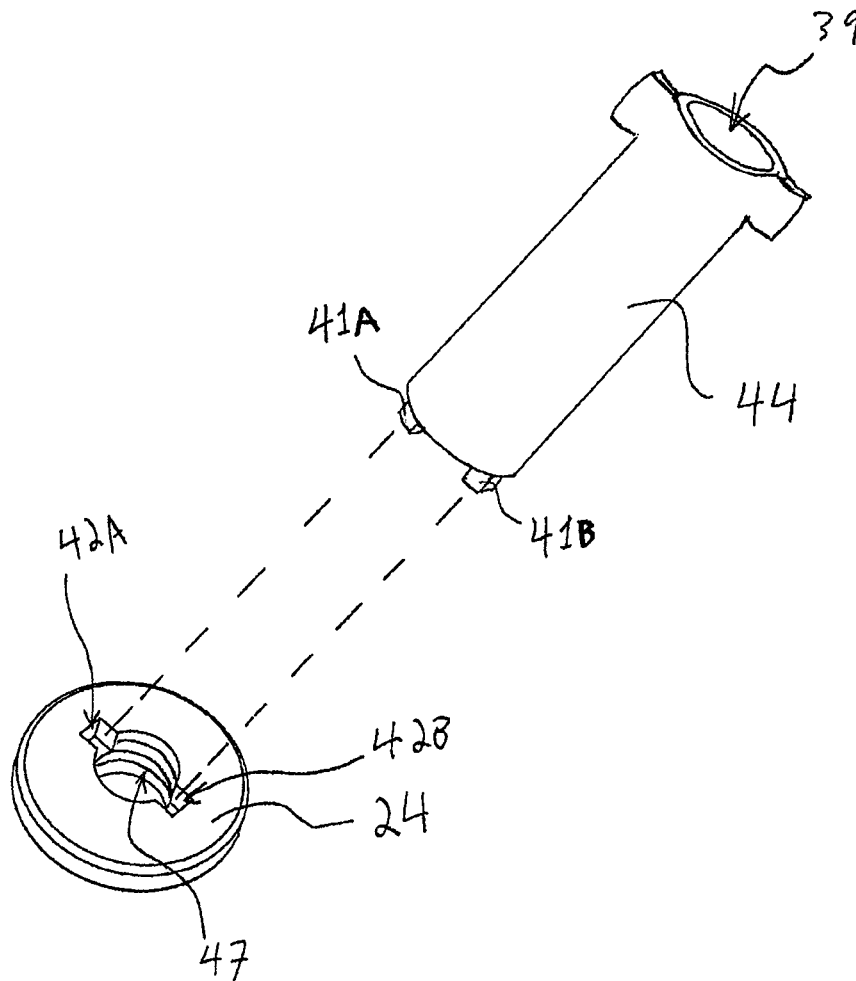
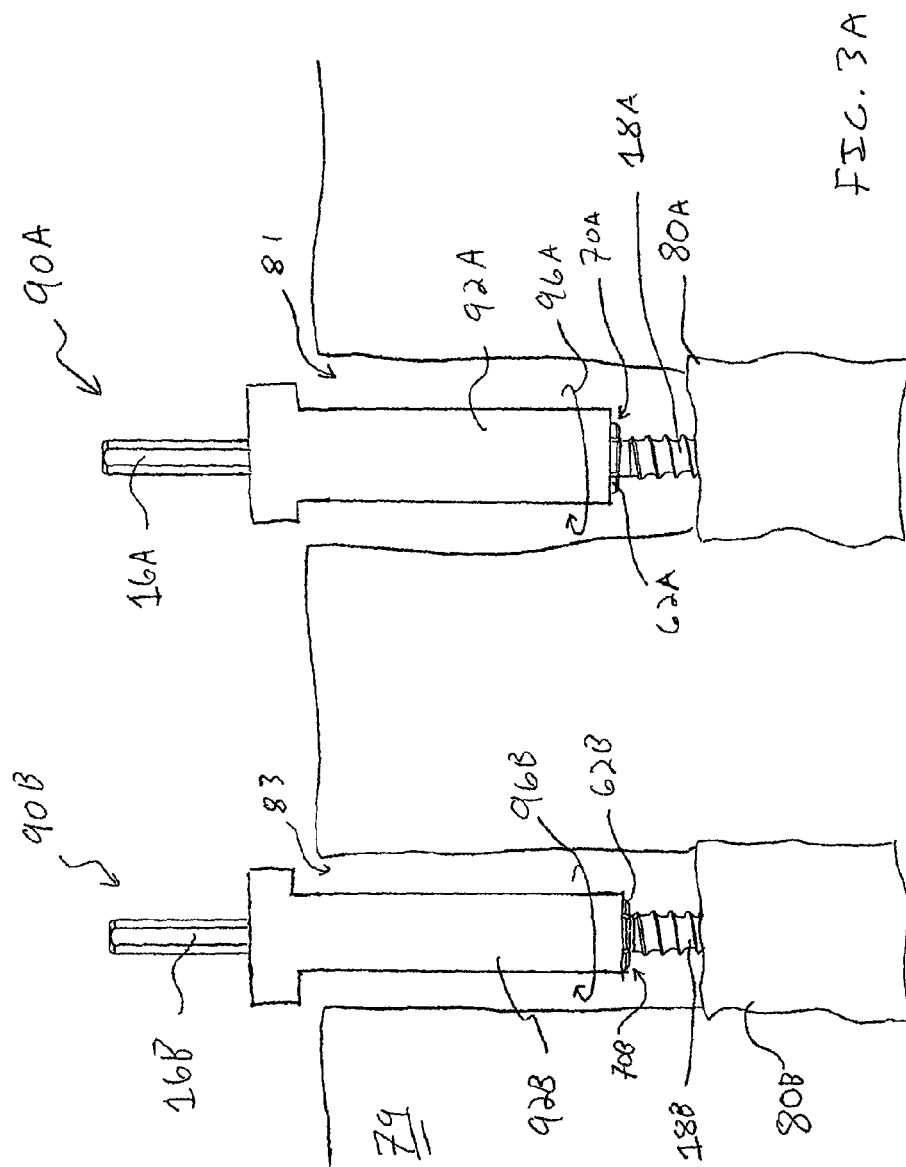


FIG. 28



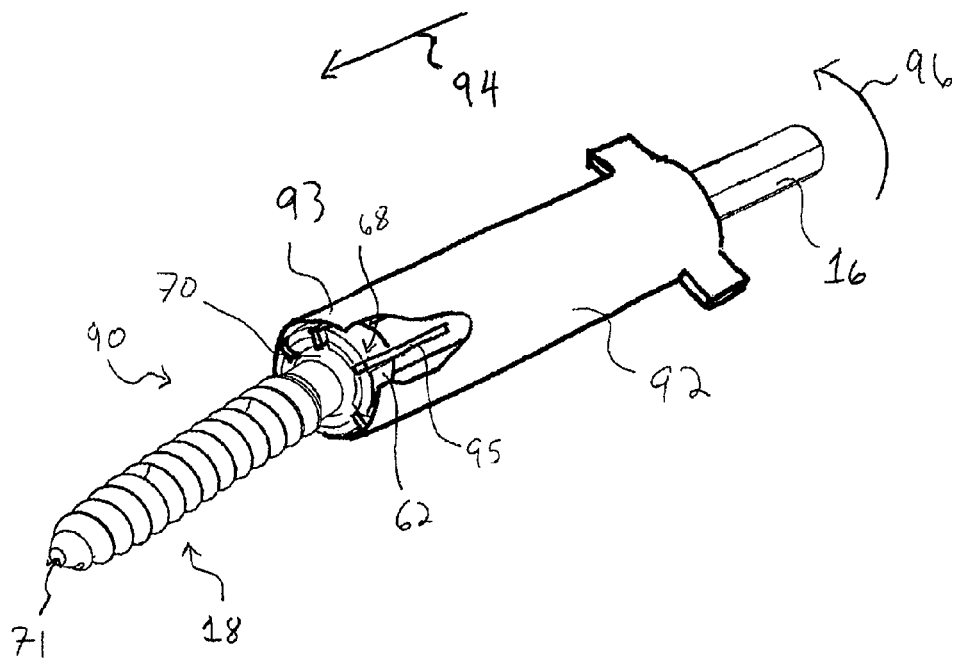


FIG. 3B

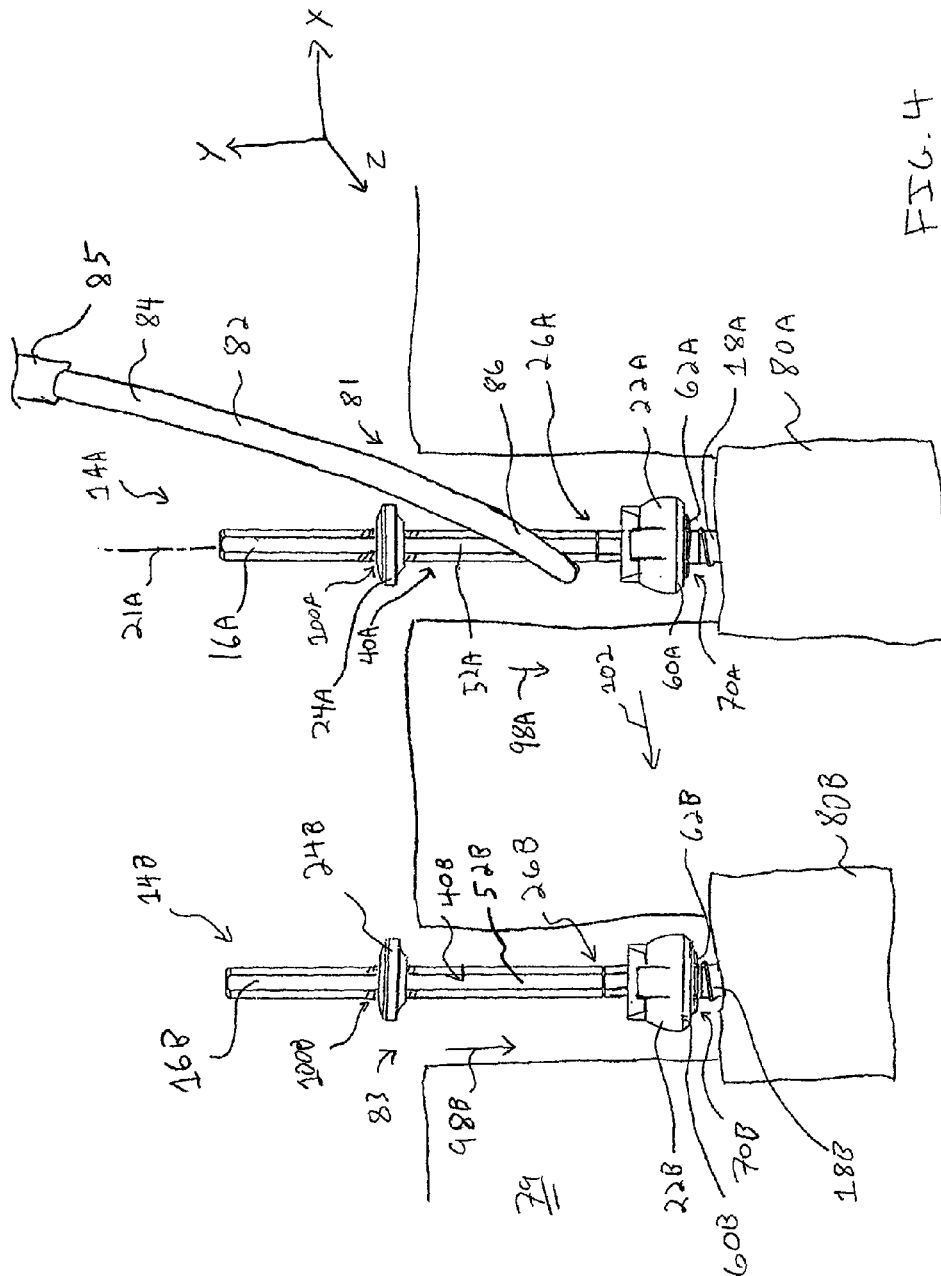


FIG. 4

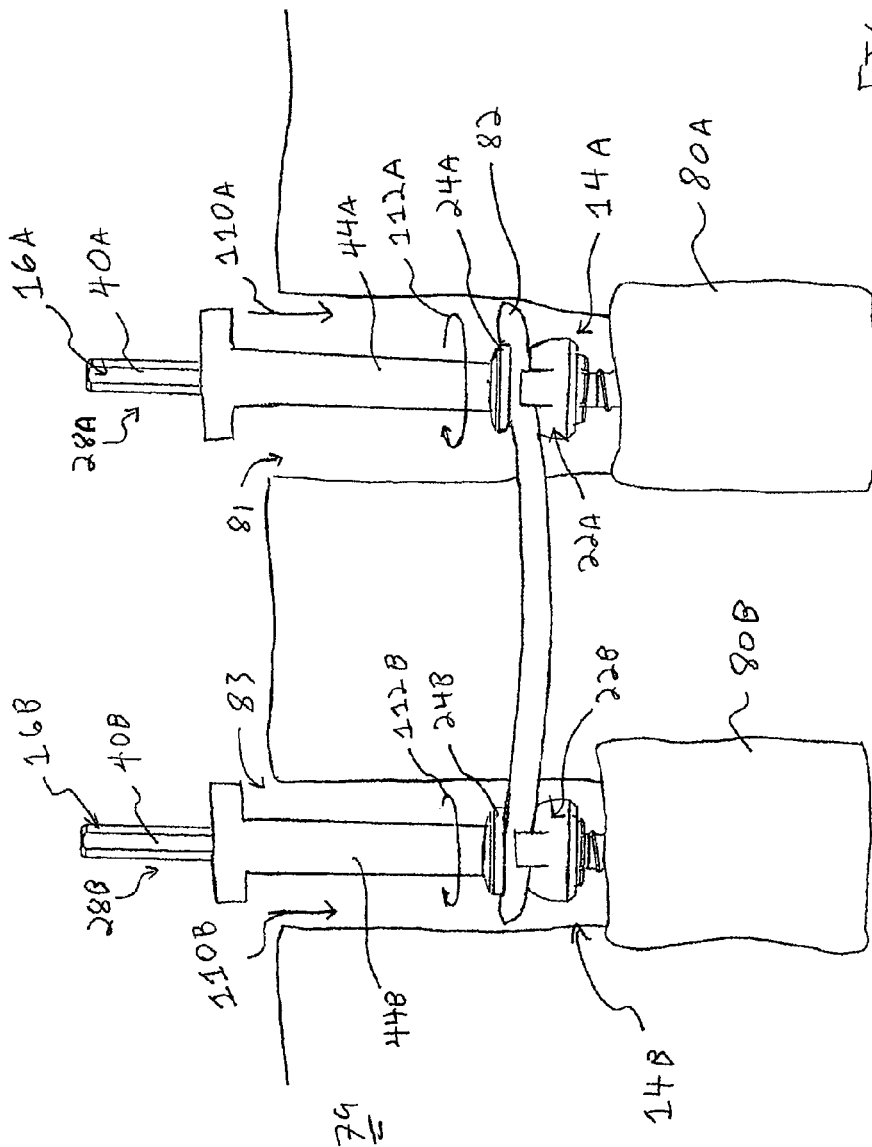
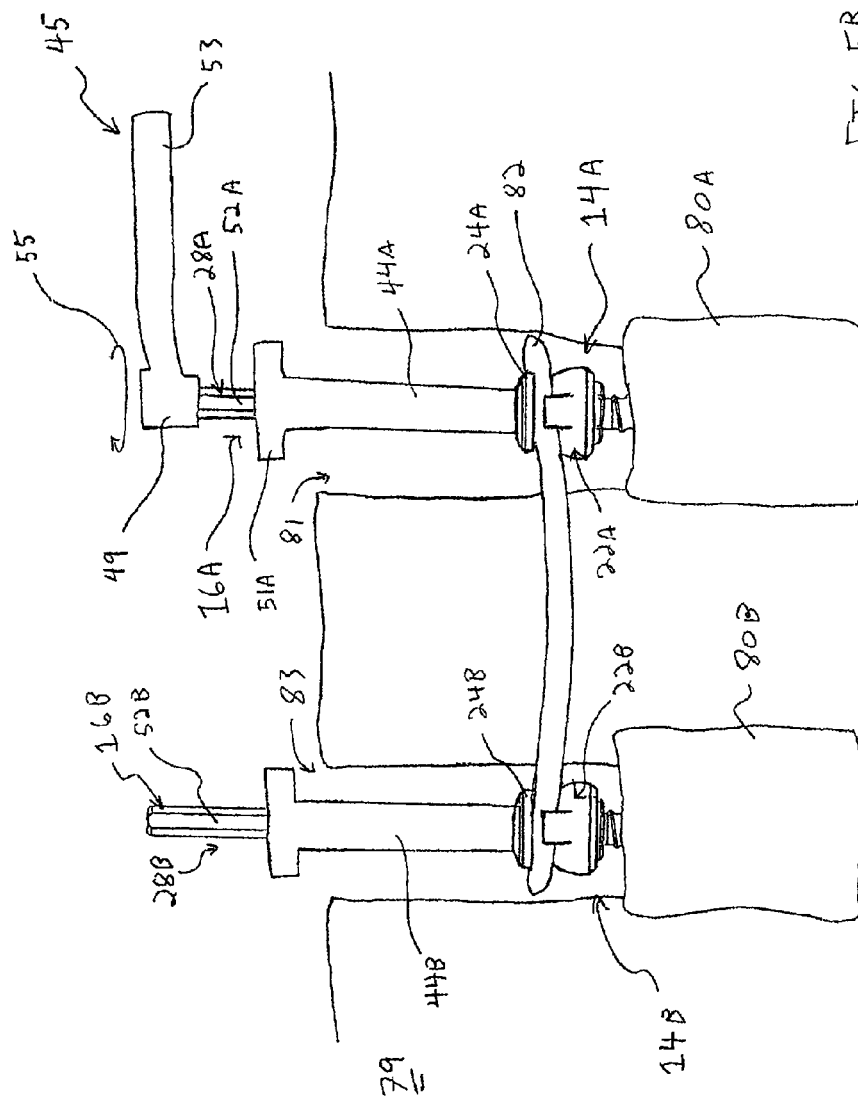
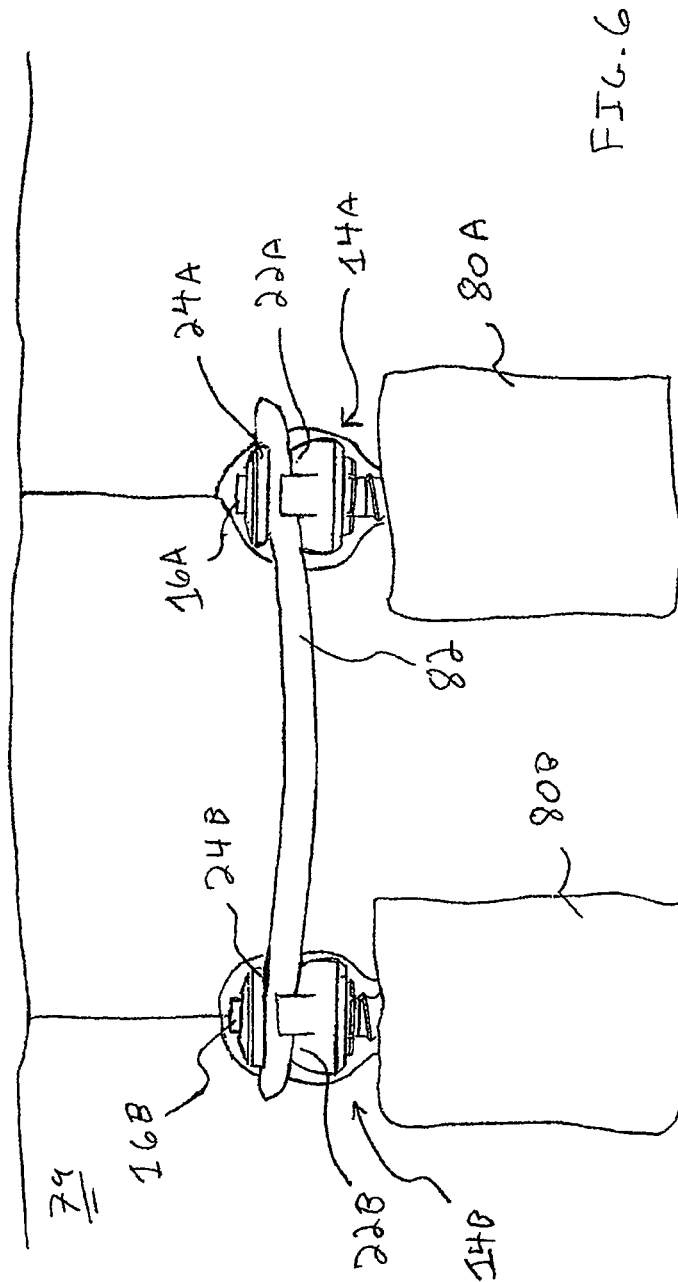
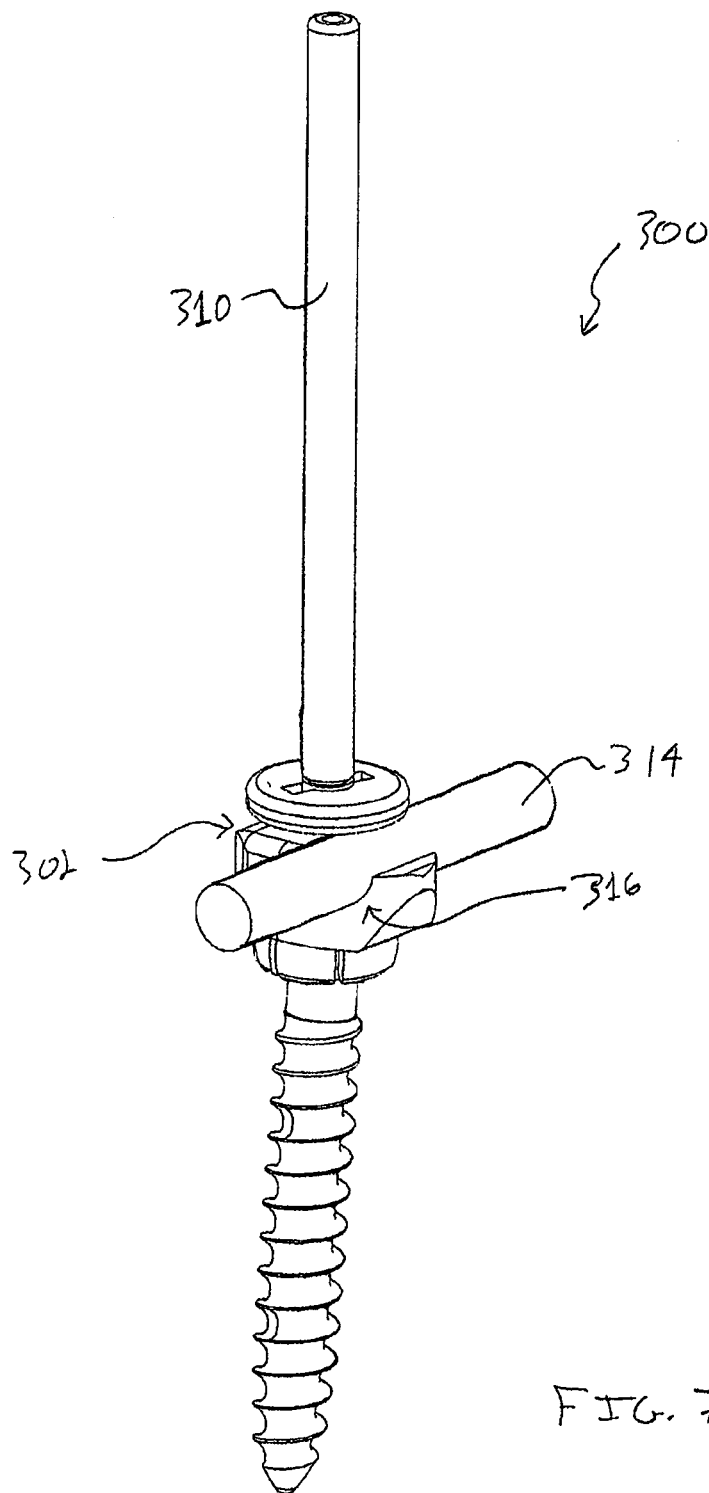
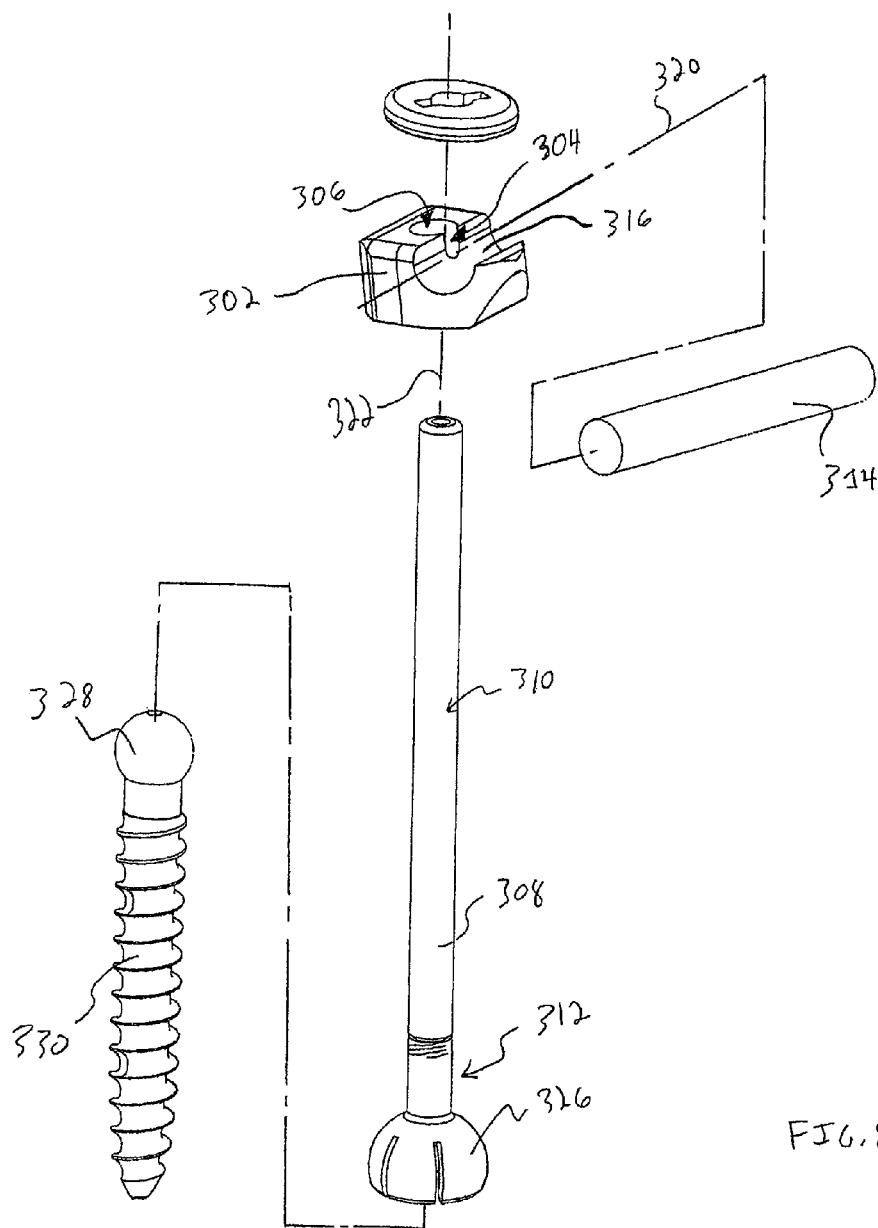


FIG. 5A









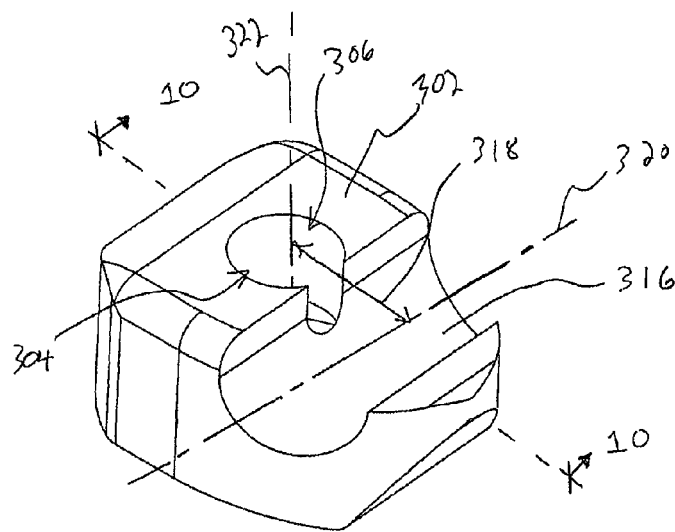


FIG. 9

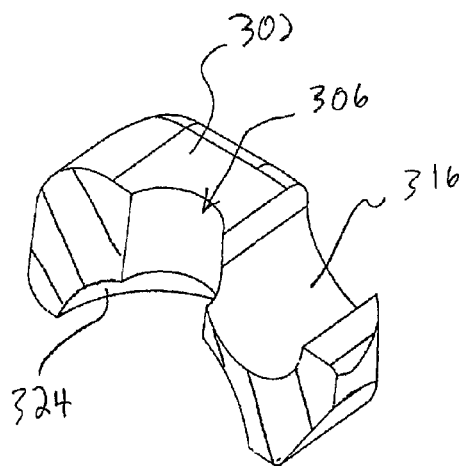
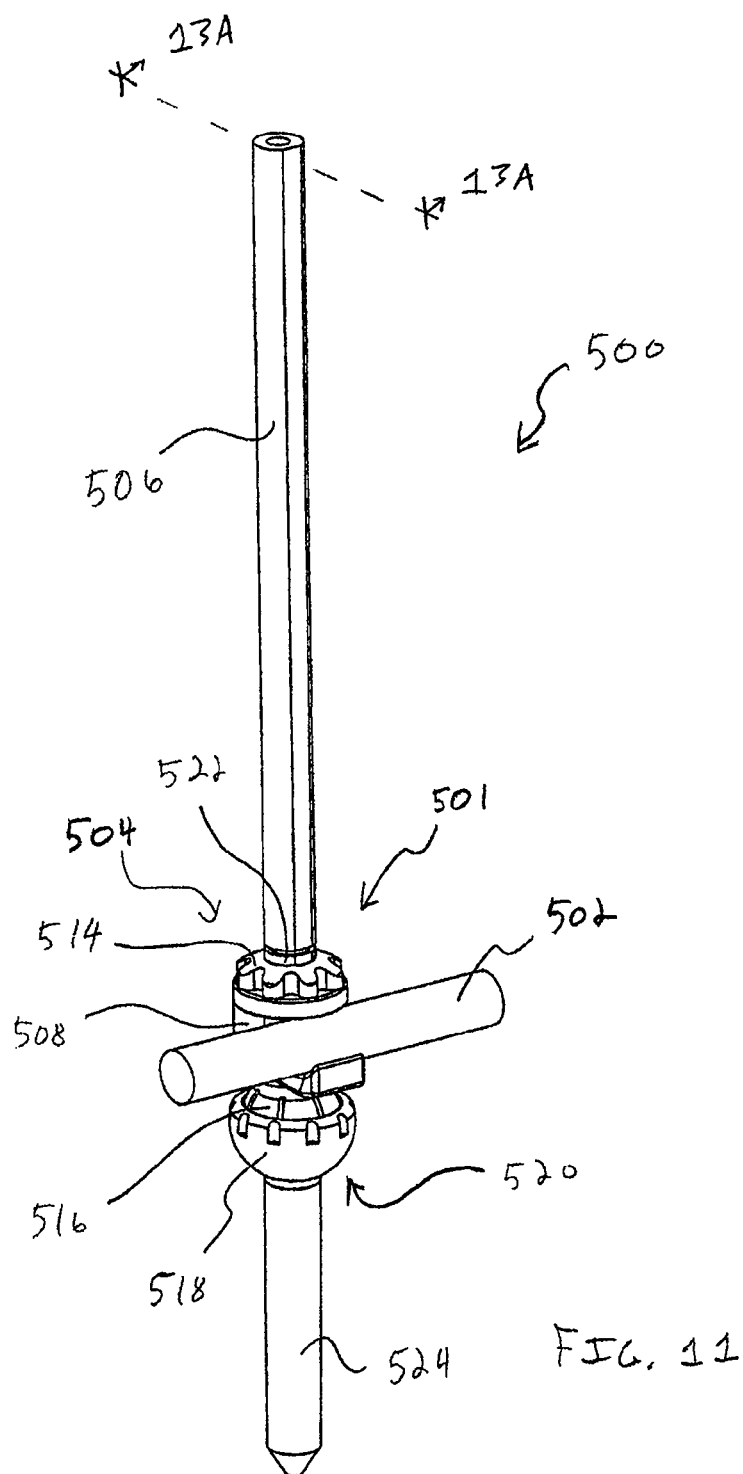
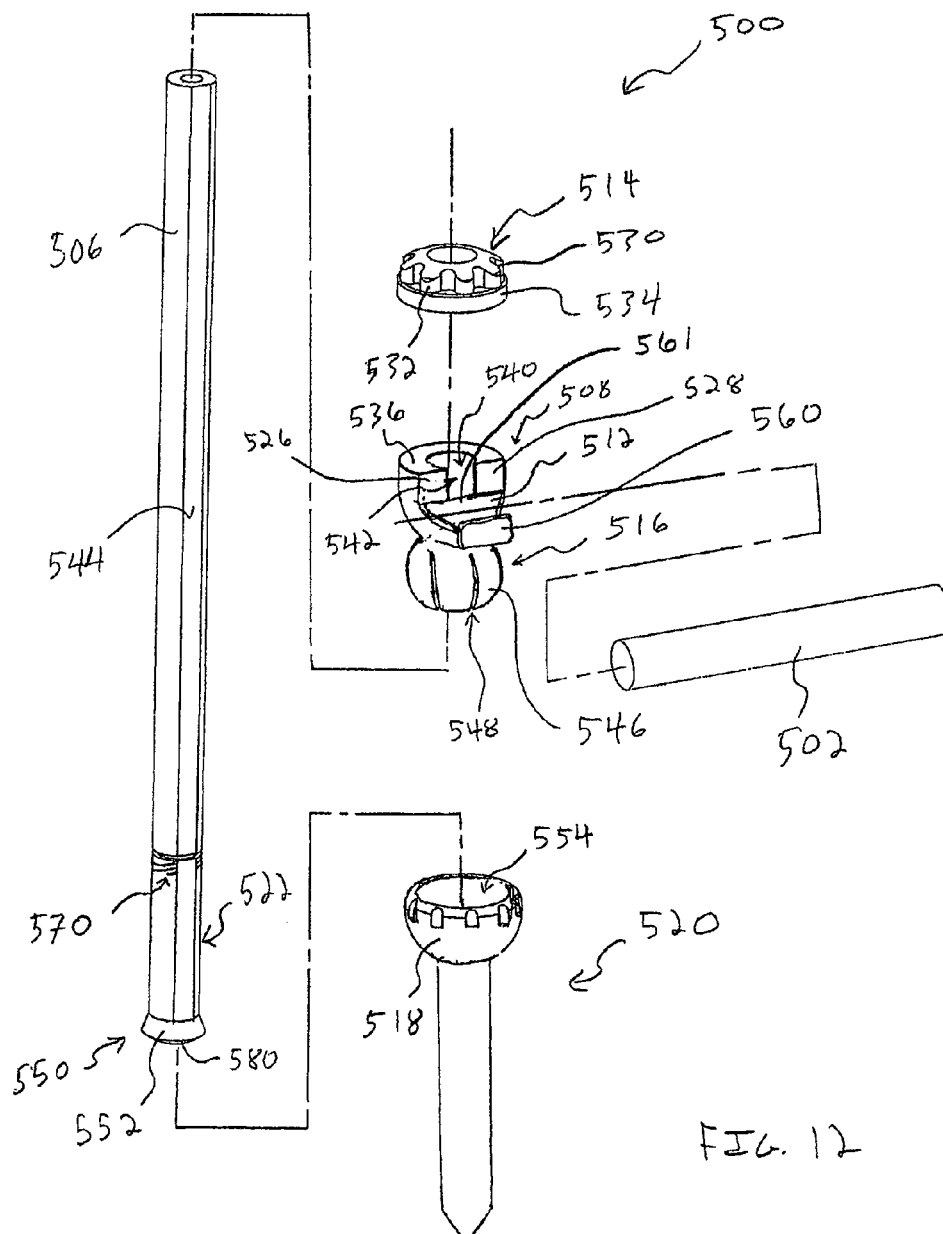
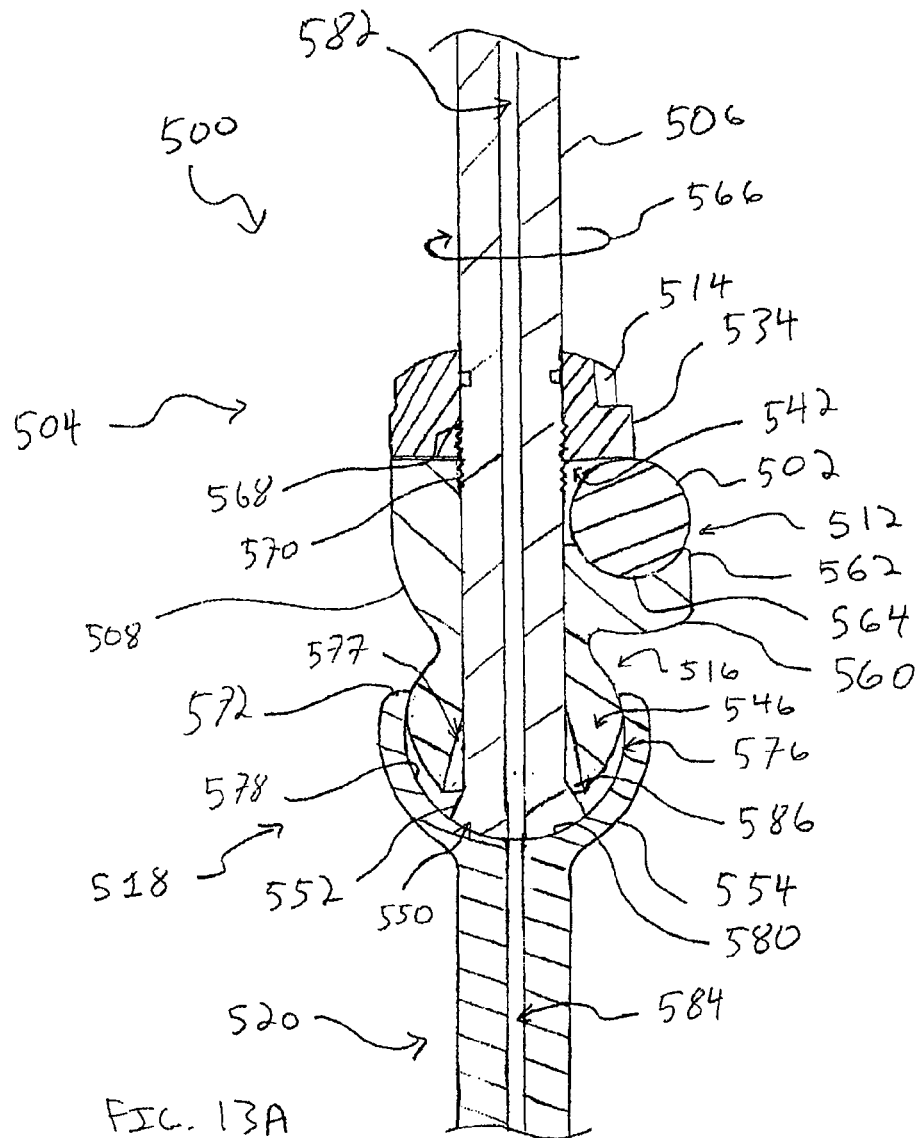


FIG. 10







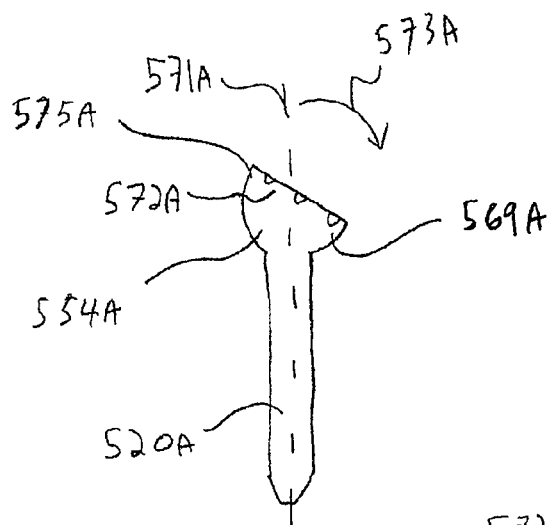


FIG 13B

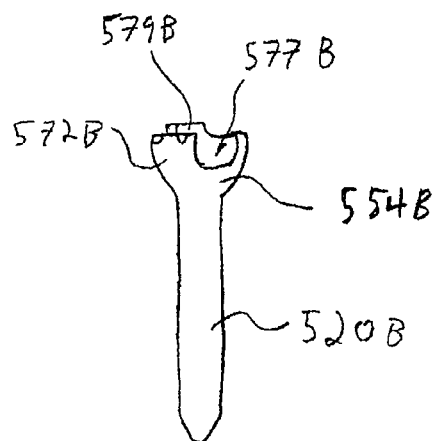
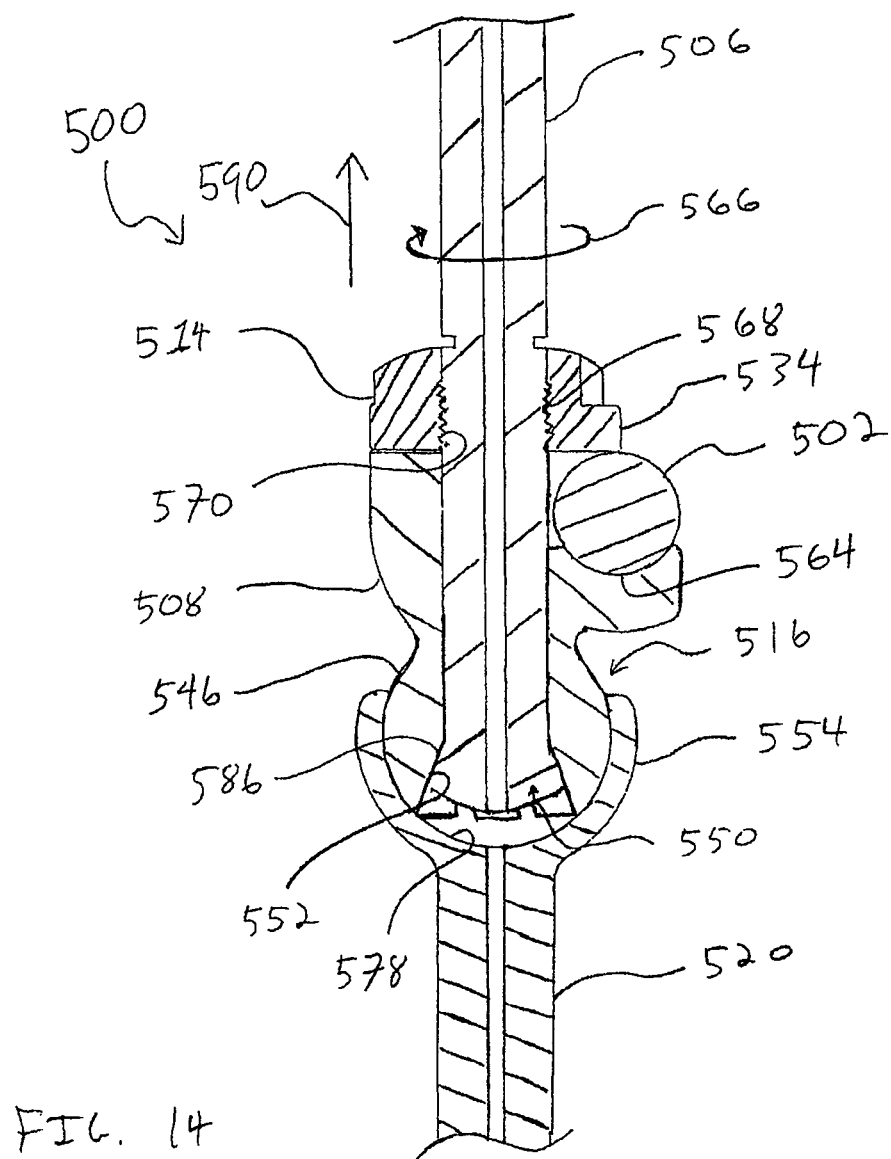
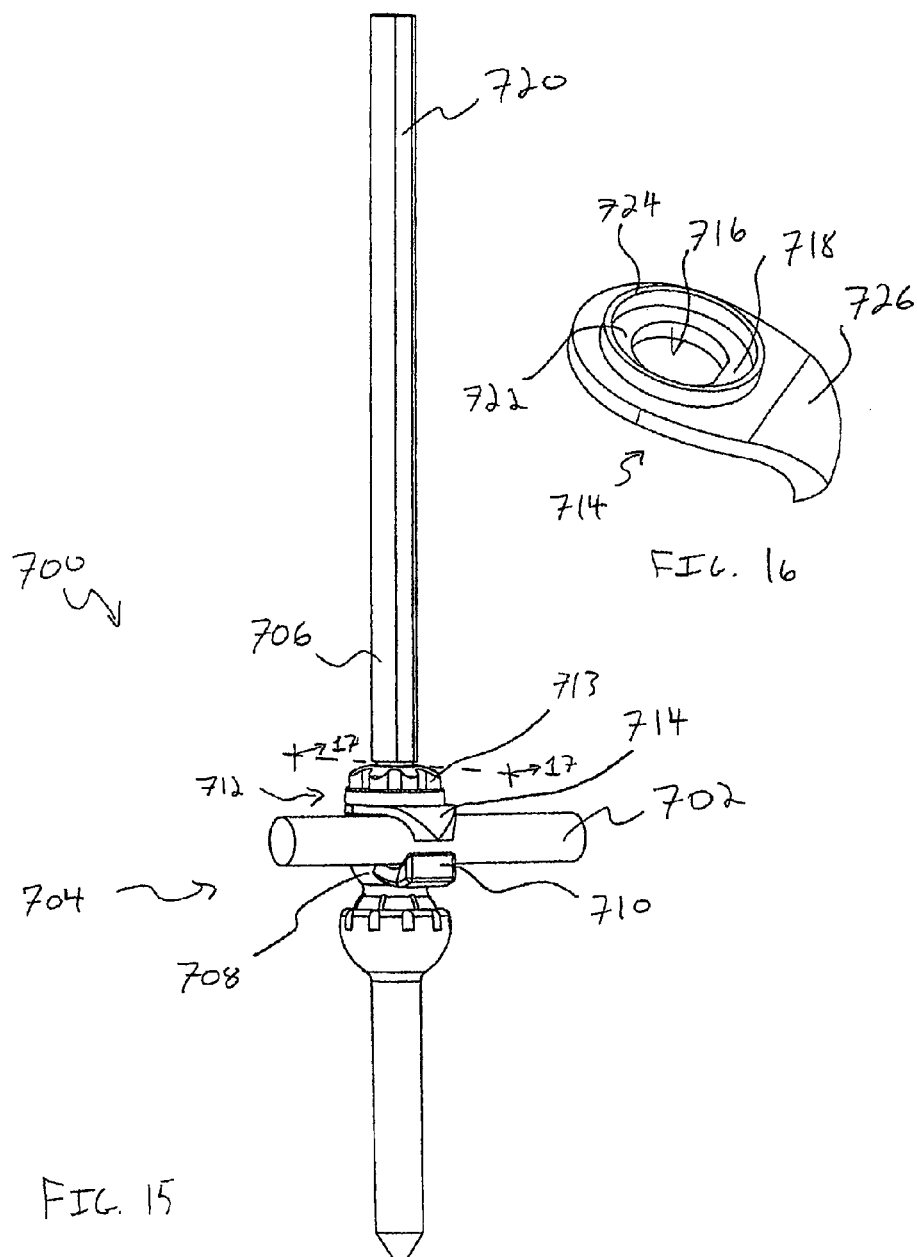
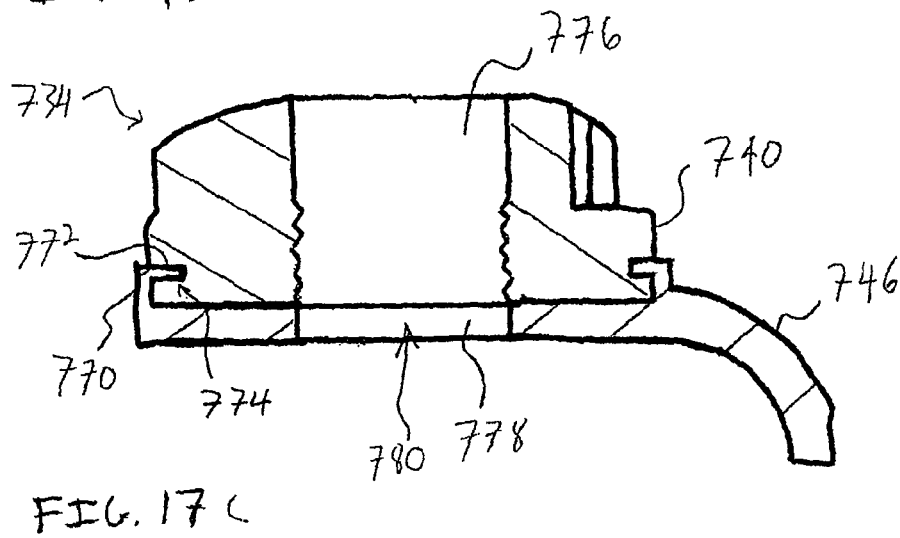
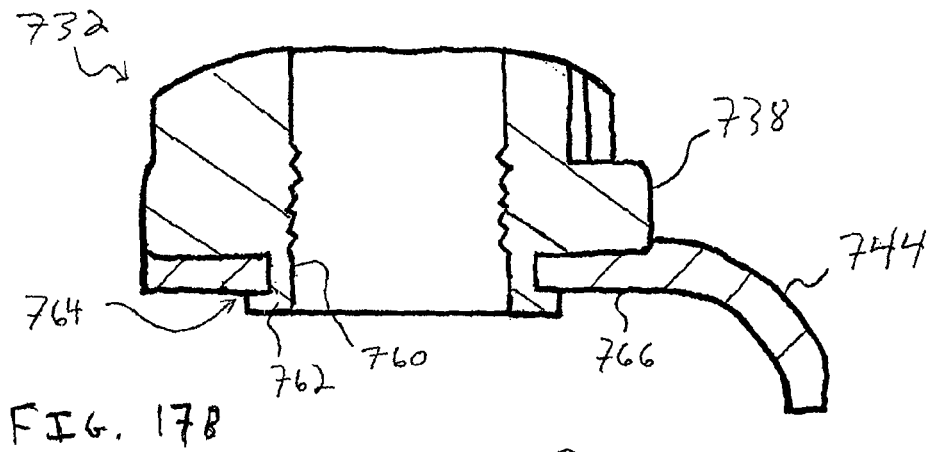
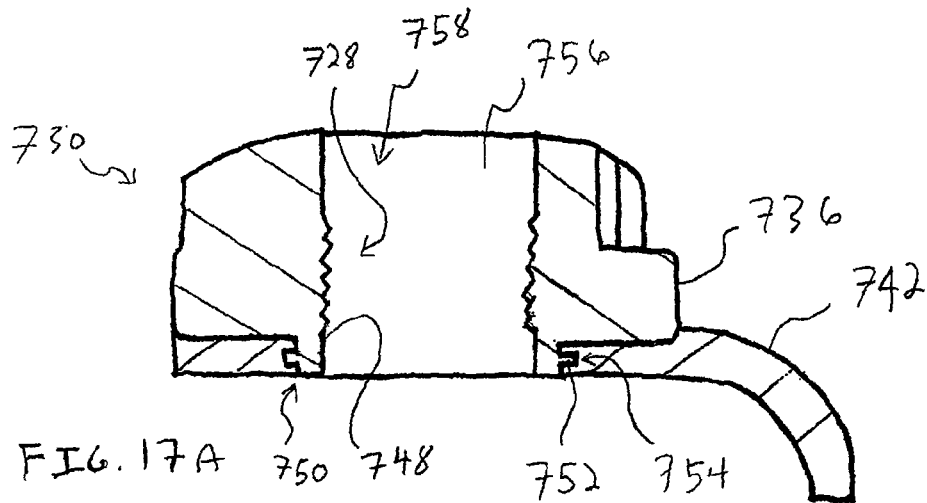


FIG. 13C







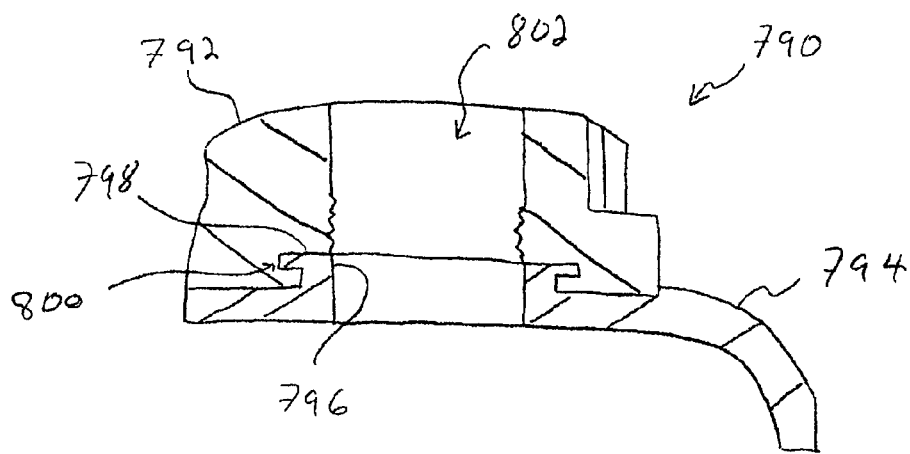
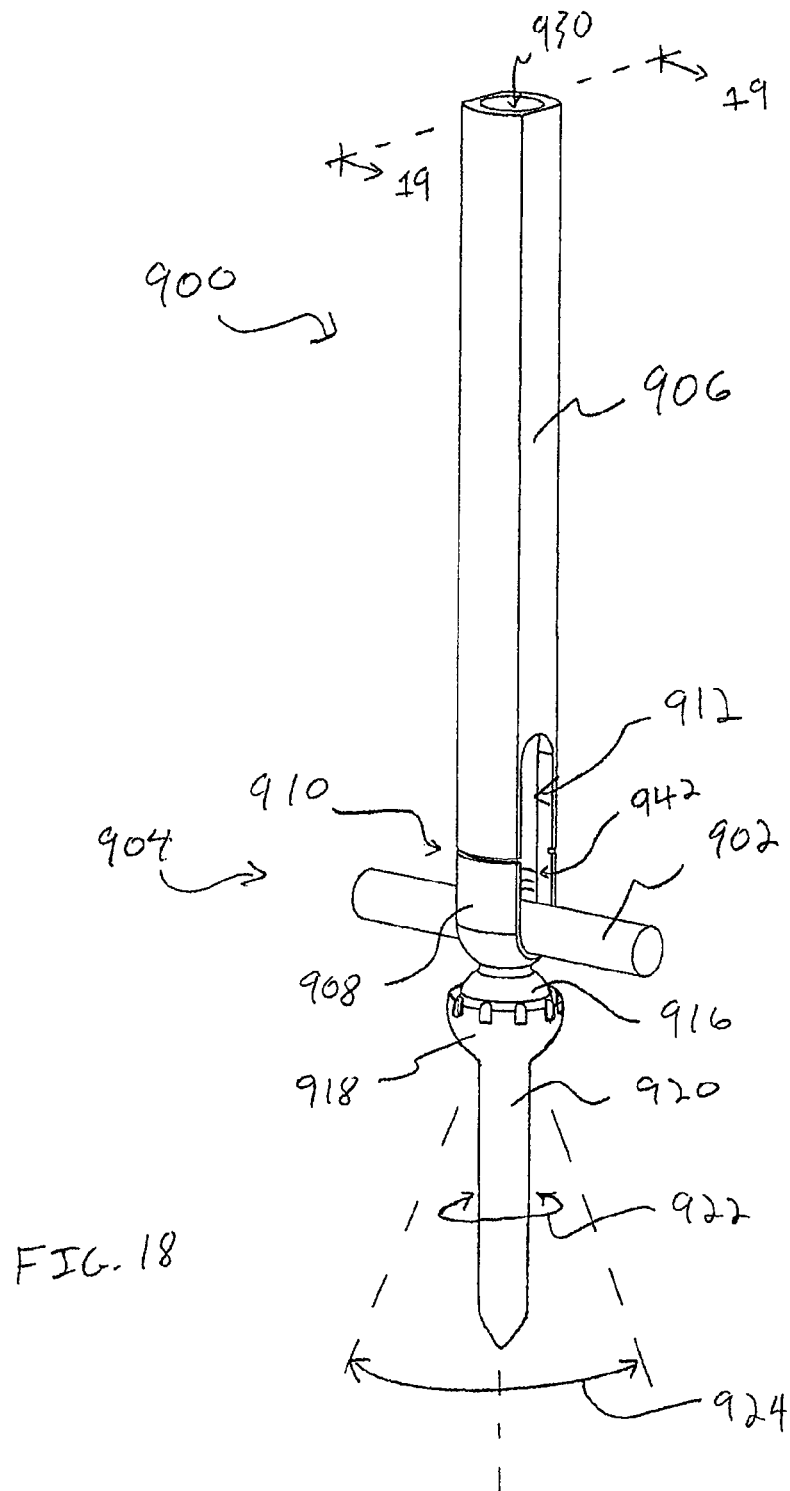


FIG. 17D



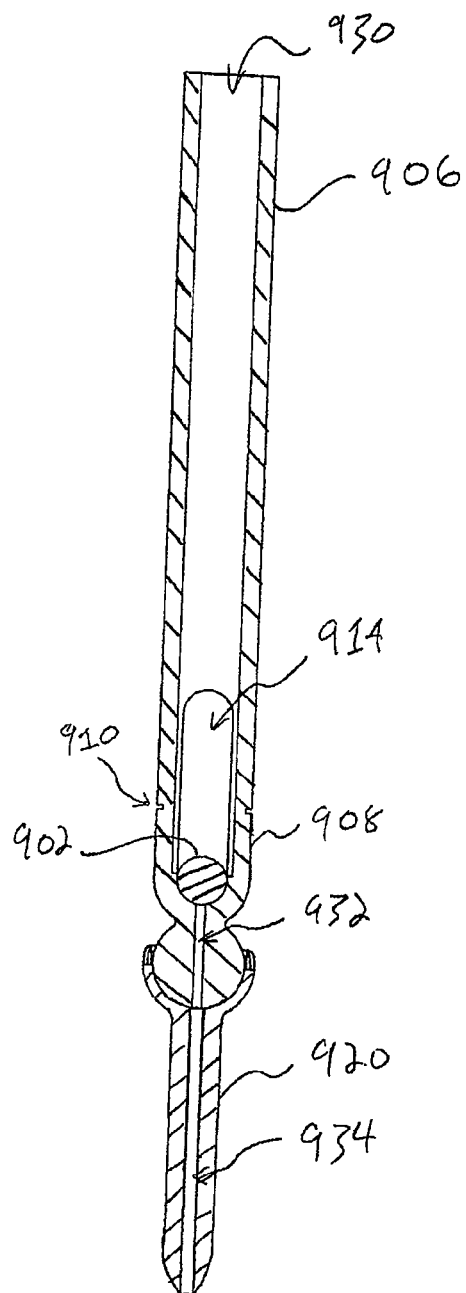


FIG. 19

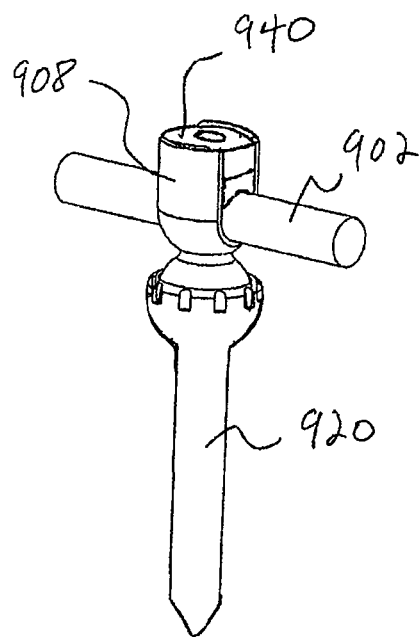


FIG. 20

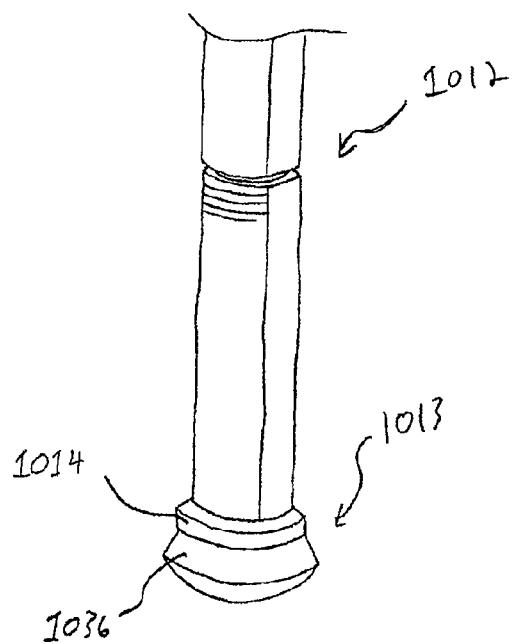


FIG. 21

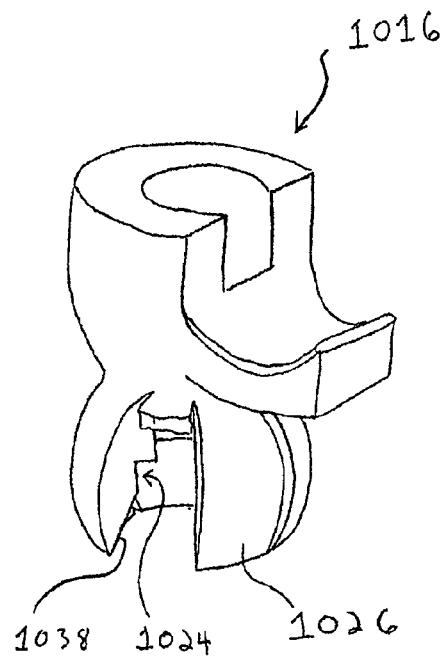


FIG. 22

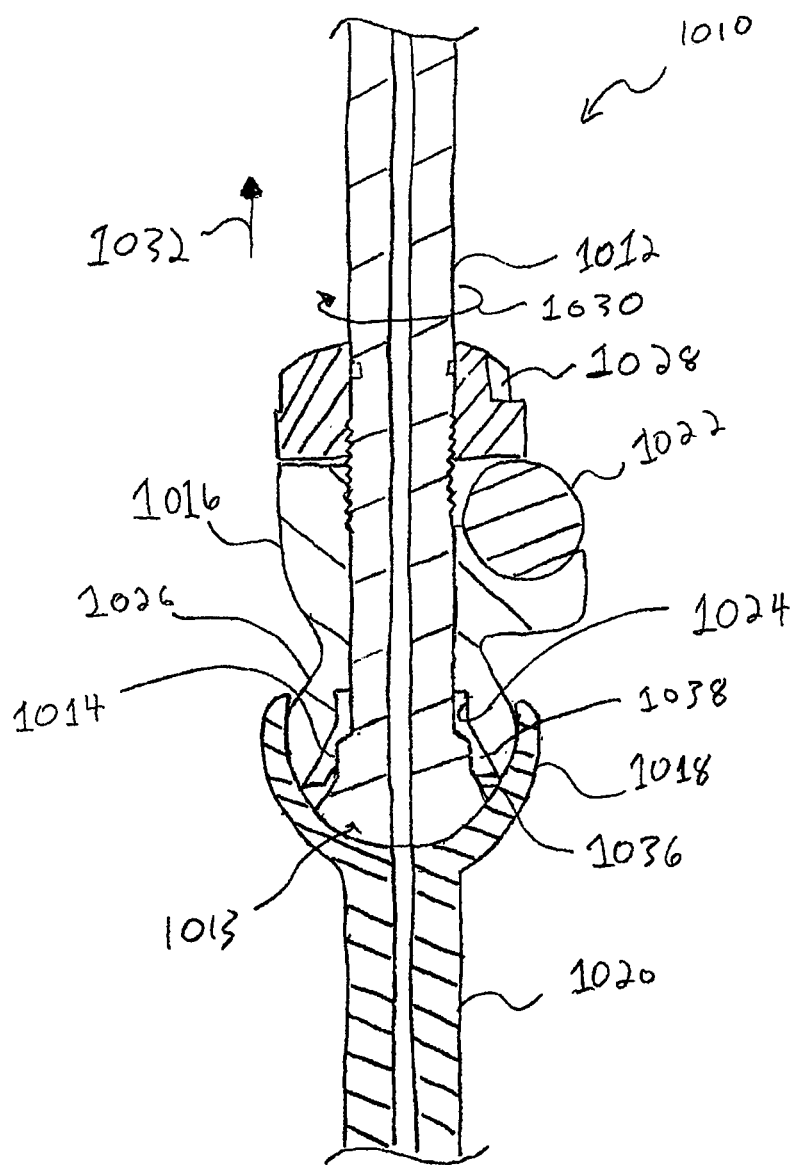


FIG. 23

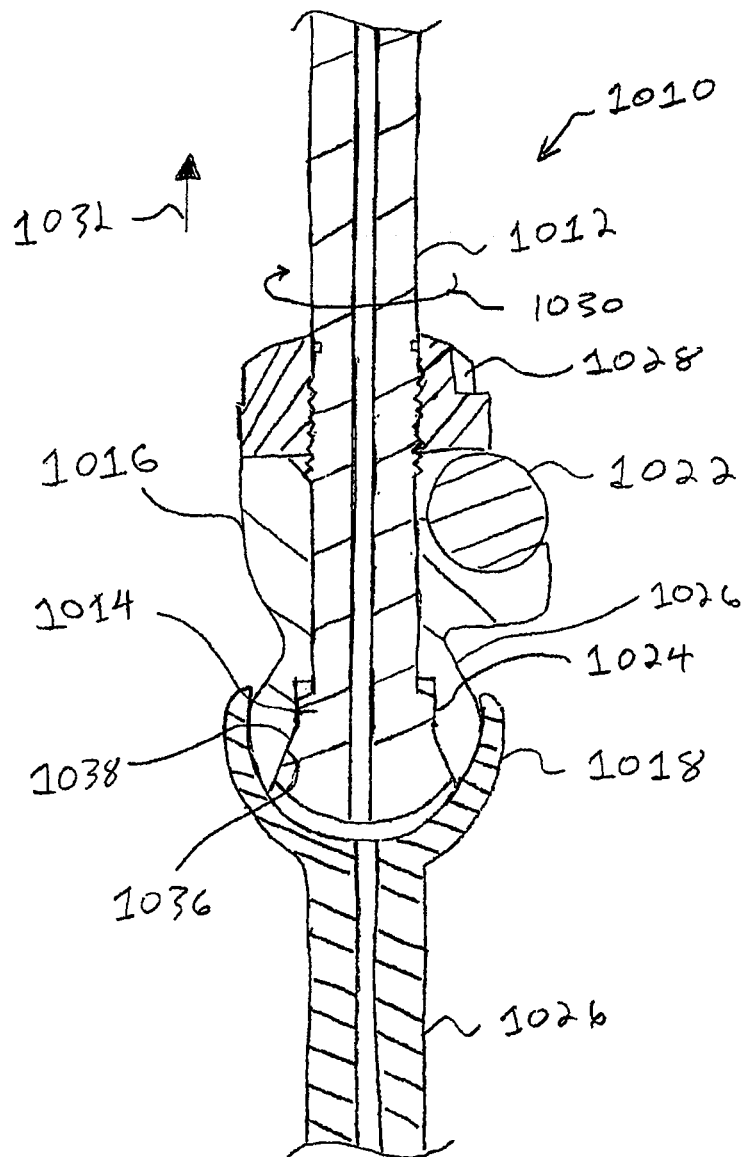


FIG. 24

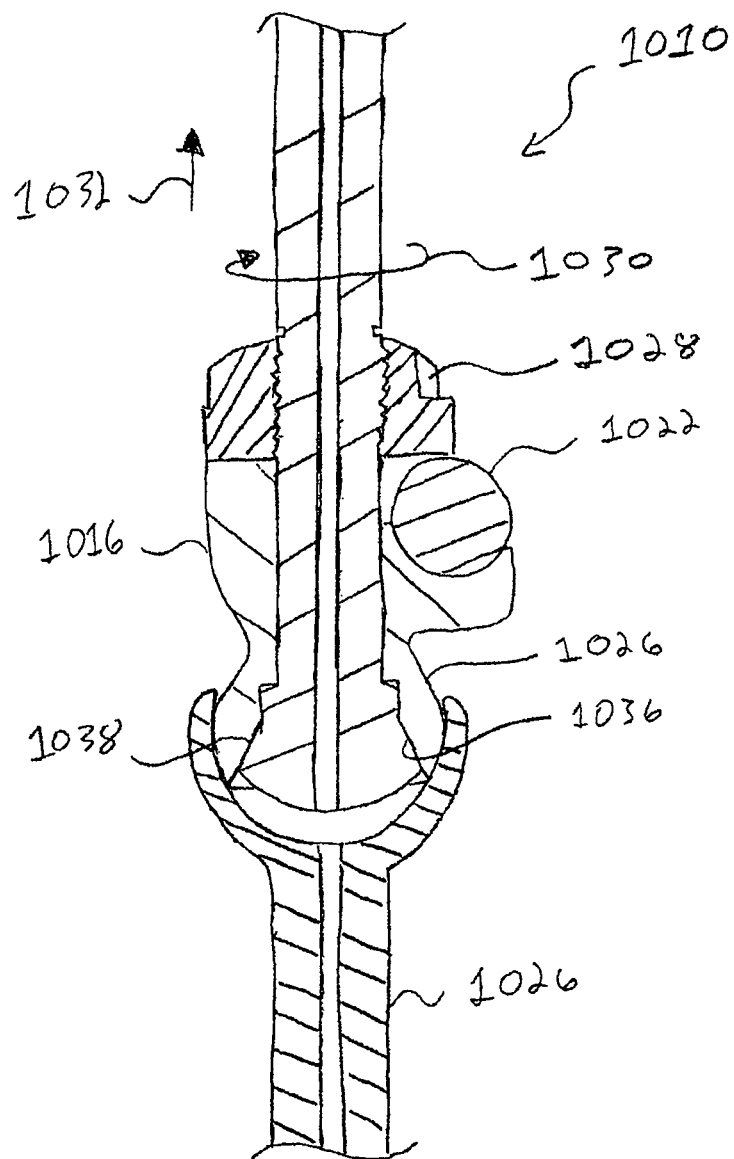


FIG. 25

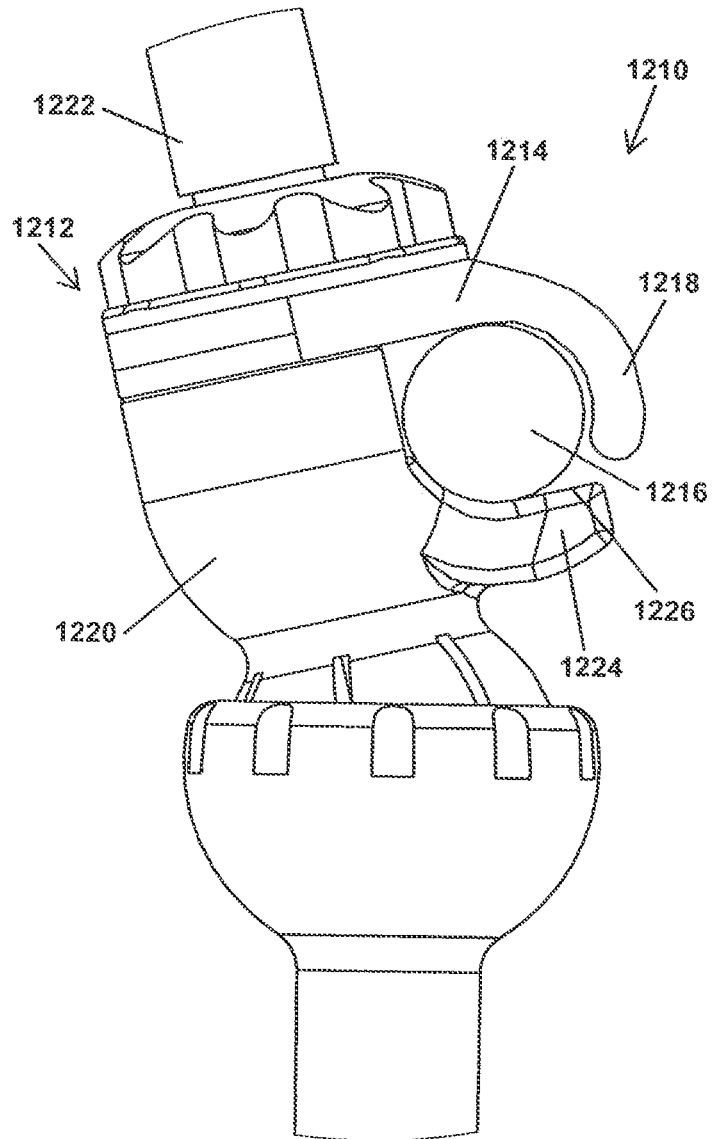


FIG. 26

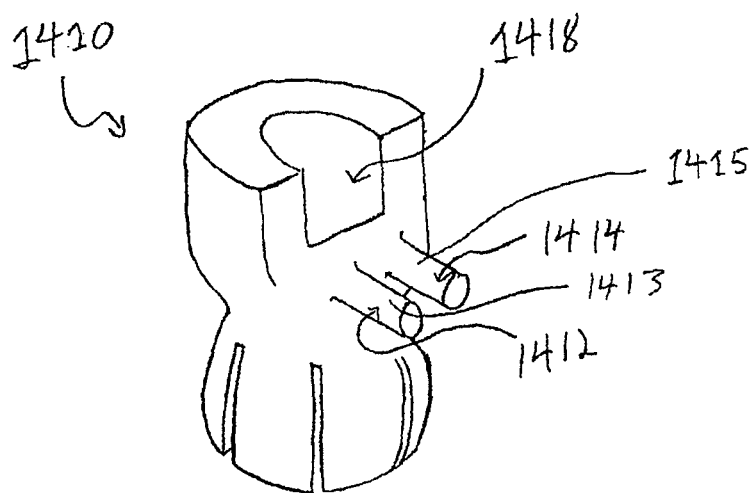


FIG. 27

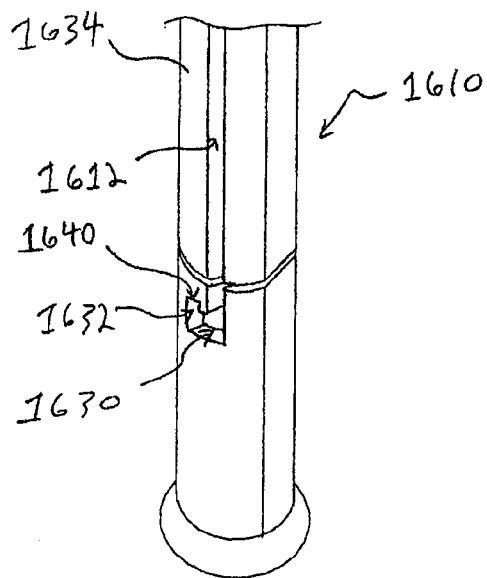


FIG. 28

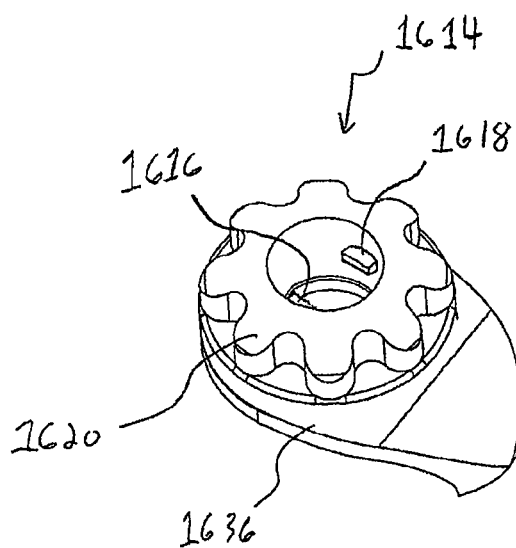


FIG. 29

1

SPINAL FIXATION SYSTEM AND METHOD**CROSS-REFERENCE TO RELATED APPLICATION**

This application claims the benefit of U.S. Provisional Patent Application No. 61/442,617, filed Feb. 14, 2011, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

This invention relates to bone fixation systems and, more particularly, to spinal fixation systems and methods used in minimally invasive procedures.

BACKGROUND OF THE INVENTION

Existing minimally invasive surgical techniques include inserting rodding systems through a small incision at the surface of the skin. These surgical techniques often use some form of an extender tube placed over the yoke of the pedicle screw to manipulate positioning of the yoke. The extender tube is also used to pass instruments for persuading the rod, inserting and advancing a locking cap, applying a counter-torque during cap locking, and removing or releasing hardware. These yoke extender tubes typically have slots in their sides to serve as a window to pass the spinal rod under the skin and through the yoke. Utilizing these surgical systems often becomes a complex task involving a multitude of surgical tools that are repeatedly connected and disconnected to achieve the desired surgical task.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, a spinal fixation system is provided that permits a spinal rod to be secured to a pair of pedicle screw assemblies during minimally invasive surgery without the use of pedicle screw yoke extender tubes. Instead, the spinal fixation system comprises two or more pedicle screw assemblies each having an upstanding elongate member for directing the spinal rod as the spinal rod is advanced subcutaneously and secured with the pedicle screw assemblies. The elongate member may be solid, cannulated, or have other cross-sectional configurations, although a solid cross-section permits the profile of the elongate member to be minimized. A distal end of the spinal rod is advanced transversely relative to the elongate members with contact between the spinal rod and the elongate members providing tactile feedback that the spinal rod is positioned adjacent the pedicle screw assemblies. The spinal rod is free to travel along, away from, toward, and around the elongate members such that the spinal rod can be maneuvered to avoid tissues and/or boney structures while seating the spinal rod on the pedicle screw assemblies. In this manner, the spinal rod may be guided into position on the pedicle screw assemblies without having to fit the spinal rod through slots of yoke extender tubes, as in some traditional approaches.

In another aspect, a spinal fixation system is provided having a pedicle screw assembly with an open seat for receiving a spinal rod, rather than a yoke as in some traditional pedicle screw assemblies. Whereas a traditional pedicle screw assembly yoke has a U-shape with walls that restrict insertion and removal of a spinal rod to generally linear paths between the yoke walls, the open seat of the instant pedicle screw assembly allows the spinal rod to be positioned on the seat using a range of substantially unrestricted insertion paths. In one form, the seat comprises an arm disposed at the

2

base of an elongate member with a planar seating surface for receiving the spinal rod. The spinal rod may be positioned on the seating surface using a number of different paths, including a vertical path generally downward along the associated elongate member, an oblique path generally downward and at an angle to the elongate member, and a horizontal path generally perpendicular to the elongate member. The ability of the seat to accommodate different insertion paths of the spinal rod provides greater flexibility to maneuver the spinal rod around tissues and/or boney structures during minimally invasive surgery. To fix the spinal rod on the seat, a locking cap is slid downward along the elongate member and engaged with a lower portion of the elongate member. The locking cap clamps the spinal rod against the seat and fixes the spinal rod relative to the associated pedicle screw assembly.

In accordance with another aspect of the present invention, a spinal fixation system comprises a pedicle screw assembly having a bone anchor, a coupling device connected to the bone anchor, and a lock device configured to secure a fixation element, such as a spinal rod, to the coupling device. The coupling device has an elongate member configured to guide the spinal rod onto the coupling device. Rather than pass tools and components through a cannula of a yoke extender tube, as in some minimally invasive surgical procedures, the tools and components of the spinal fixation system travel along exterior surfaces of the elongate members. In a preferred embodiment, the elongate member has an integrally releasable or break-away connection with the coupling device to permit the elongate member to be broken off after the spinal rod has been secured to the coupling device.

In another aspect, a spinal fixation system having a pedicle screw assembly and a spinal rod is provided that allows one-step fixation of the spinal rod relative to a vertebral bone. The pedicle screw assembly has a coupling device connected to a bone screw with an elongate member for guiding the spinal rod onto the coupling device. The coupling device has a seat for receiving the spinal rod, the seat preferably being in the form of a body having a curved surface, a flat surface, a ledge, an arm, or other configuration. The coupling device comprises a locking cap that travels along the elongate member and connects to a lower end of the elongate member to fix the spinal rod to the coupling device and substantially simultaneously fix the coupling device relative to the bone screw. In one preferred embodiment, the pedicle screw assembly has a ball and socket connection between the coupling device and the bone screw. Engaging the locking cap with the lower end of the elongate member fixes the ball and socket connection against movement and rigidly connects the spinal rod to the vertebral bone.

A method is also provided that permits a surgeon to visually align a spinal rod with one or more elongate members extending above a patient's skin before advancing the spinal rod through an incision and permits the surgeon to use outer surfaces of the one or more elongate members as guides while advancing the spinal rod subcutaneously. Initially, a small incision is made in a patient's skin and other tissues adjacent a pair of vertebral bones. A guide wire is inserted through each of the incisions into contact with a respective vertebral bone before serial dilators are passed over the guide wires and into contact with the vertebral bones. A tubular member may optionally be fit over the dilators and secured to the vertebral bones to form a working channel. A pair of bone screws and coupling devices connected thereto are advanced through the working channels and driven into engagement with the vertebral bones. The coupling devices have upstanding, elongate members sized to extend above the skin of the patient from within the working channels and permit the surgeon to visu-

3

alize the location of the vertebral bones via the elongate members. The surgeon may consider the distance between the elongate members in determining the length of the spinal rod selected to secure the vertebral bones. Imaging devices, such as x-ray machines, or internal or external measuring devices may also be used to determine the length of the spinal rod desired to secure the vertebral bones. Further, the elongate members extending above the skin permit the surgeon to visually align the spinal rod with a desired path between the elongate members, e.g., the spinal rod is to travel on the left lateral side of both elongate members.

The method may further include using a rod inserter tool to advance a distal end portion of a spinal rod toward one of the vertebral bones through the associated working channel. The distal end of the spinal rod is advanced along an outer surface of the elongate member positioned in the working channel until reaching a seat of the coupling device which is disposed at the base of the elongate member. The distal end of the spinal rod may then be advanced beneath the skin and other tissues of the patient toward the other bone screw. As the spinal rod travels subcutaneously, the surgeon is free to move the spinal rod along, away from, toward, and around the outer surface of the elongate member as needed to maneuver the distal end of the spinal rod around the tissues and boney structures adjacent the vertebral bones. The distal end of the spinal rod may be brought into contact with an outer surface of the other elongate member to provide a tactile indication that the distal end has reached the other pedicle screw assembly. Further, a proximal end of the spinal rod may be brought into contact with the outer surface of the adjacent elongate member to provide a tactile indication that the proximal end of the spinal rod is positioned above the associated pedicle screw assembly. The spinal rod may be lowered along the outer surfaces of the elongate members until the distal end engages the seat of one of the coupling devices and the proximal end engages the seat of the other coupling device. Next, a locking cap is slid over and along the outer surface of each elongate member and engaged with a lower end of the elongate member to fix the spinal rod to the coupling device. An upper end of each of the elongate members may then be broken off or released, then removed before the working channels are closed.

In accordance with another aspect, a method of using a spinal fixation system is also provided wherein the spinal fixation system comprises a bone screw, a spinal rod, and a coupling device for connecting the spinal rod to the bone screw. The spinal fixation system provides multi-step locking of a spinal rod to a bone screw including an initial configuration for installing the bone screw, an intermediate fixation configuration for loosely connecting the spinal rod to the bone screw, and a final locking configuration where the spinal rod is fixed to the bone screw. In the initial configuration, the coupling device is pivotally and rotatably connected to the bone screw such that the connected coupling device and bone screw may be passed through a working channel and secured to a bone. The spinal rod is advanced through the working channel and positioned on a seat of the coupling device before a locking cap is slid downward along an elongate member of the coupling device. The locking cap is engaged with a lower portion of the elongate member to loosely capture the spinal rod on the seat of the coupling device. Next, the elongate member is manipulated to shift the spinal fixation system to the intermediate fixation configuration and rigidly fix the connection between the coupling device and the bone screw. In an alternative approach, the elongate member is manipulated to shift the spinal fixation system to the intermediate fixation configuration before the spinal rod is positioned on

4

the seat and the locking cap is used to capture the spinal rod on the seat. With the spinal fixation system in the intermediate fixation configuration, the coupling device is fixed relative to the bone screw while the locking cap permits the spinal rod to be slidably repositioned on the seat. The locking cap is then manipulated to shift the spinal fixation system to a final locking configuration and clamp the spinal rod against the seat of the coupling device. At this point, the spinal rod, coupling device, and pedicle screw are rigidly fixed relative to each other.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a spinal fixation system in accordance with the present invention showing a spinal rod held by a pedicle screw assembly;

FIG. 2A is an exploded perspective view of the spinal fixation system of FIG. 1 showing a locking cap and a saddle body that travel along a guide member and a socket of the guide member that connects to a head of a bone screw;

FIG. 2B is an exploded perspective view of the locking cap of FIG. 2A and a rod locking sleeve for manipulating the locking cap, FIG. 2B showing an engagement interface between the rod locking sleeve and the locking cap;

FIG. 3A is a side elevational view of a pair of pedicle screw subassemblies including a bone screw and a guide member similar to the components of the pedicle screw assembly of FIG. 1, with FIG. 3A showing the pedicle screw subassemblies being connected to respective vertebral bones beneath a patient's skin using driver sleeves;

FIG. 3B is a perspective view of a pedicle screw subassembly and the driver sleeve of FIG. 3A having a portion of the driver sleeve removed to show internal longitudinal fins of the driver sleeve;

FIGS. 4-6 are a series of side elevational views of the pedicle screw subassemblies of FIG. 3A illustrating an exemplary procedure for securing a spinal rod to the pedicle screw subassemblies;

FIG. 7 is a perspective view of a spinal fixation system in accordance with another form of the present invention showing a spinal rod held by a pedicle screw assembly;

FIG. 8 is an exploded perspective view of the spinal fixation system of FIG. 7 showing a locking cap and a saddle body that travel along a guide member and a socket of the guide member that connects to a head of a bone screw;

FIG. 9 is a perspective view of the saddle body of FIG. 8 showing an open seating surface of the saddle body;

FIG. 10 is a cross-sectional view taken across line 10-10 in FIG. 9 that shows a throughbore of the saddle body opening into an engagement cup;

FIG. 11 is a perspective view of a spinal fixation system in accordance with another form of the present invention showing a spinal rod held within a pedicle screw assembly;

FIG. 12 is an exploded perspective view of the spinal fixation system of FIG. 11 showing a locking cap and a pivot body that travel along a guide member and a distal end of the guide member that is disposed within the pivot body;

FIG. 13A is an enlarged, fragmented cross-sectional view of the spinal fixation system of FIG. 11 taken across line 13A-13A in FIG. 11 that shows the spinal rod received within the pedicle screw assembly before the locking cap is tightened to fix the spinal rod to the pedicle screw assembly;

FIGS. 13B and 13C are side elevational views of alternative embodiments of a bone screw of the pedicle screw assembly of FIG. 11;

FIG. 14 is a cross-sectional view of the spinal fixation system of FIG. 11 that is similar to FIG. 13A and shows the

5

pedicle screw assembly after the locking cap is tightened to fix the spinal rod within the pivot body;

FIG. 15 is a perspective view of a spinal fixation system in accordance with another form of the present invention showing a spinal rod held by a pedicle screw assembly by a locking cap;

FIG. 16 is a perspective view of a lower capture portion of the locking cap of FIG. 15;

FIGS. 17A-17D are cross-sectional views of the locking cap of FIG. 15 taken along line 17-17 in FIG. 15 that illustrate alternative embodiments of a connection between an upper portion of the locking cap and the lower capture portion;

FIG. 18 is a perspective view of a spinal fixation system in accordance with another form of the present invention showing a range of motion of a bone screw of the spinal fixation system;

FIG. 19 is a cross-sectional view of the spinal fixation system of FIG. 18 taken across line 19-19 in FIG. 18 showing a ball-and-socket connection between a yoke of the spinal fixation system and the bone screw;

FIG. 20 is a perspective view of the spinal fixation system of FIG. 18 showing a locking cap capturing a spinal rod within the yoke;

FIG. 21 is a perspective view of a guide member similar to the guide member of the spinal fixation system of FIG. 11, with FIG. 21 showing a step of the guide member;

FIG. 22 is a perspective view of a pivot body similar to the pivot body of the spinal fixation system of FIG. 11, with FIG. 22 showing a portion of the pivot body removed to show an interior recess that is complimentary to the step of the guide member of FIG. 21;

FIGS. 23-25 are cross sectional views of a spinal fixation system in accordance with another form of the present invention including the guide member of FIG. 21 and the pivot body of FIG. 22, with FIGS. 23-25 showing a process of fixing a spinal rod to a pedicle screw assembly;

FIG. 26 is a side elevational view of a spinal fixation system in accordance with another form of the present invention showing a locking cap lower capture portion extending around a spinal rod;

FIG. 27 is a perspective view of a pivot body similar to the pivot body of the spinal fixation system of FIG. 26;

FIG. 28 is a perspective view of a guide member similar to the guide member of the spinal fixation system of FIG. 15, with FIG. 28 showing a longitudinal channel of the guide member; and

FIG. 29 is a perspective view of a locking cap for use with the guide member of FIG. 28.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In FIG. 1, a spinal fixation system 10 in accordance with one form of the present invention is depicted. The spinal fixation system 10 comprises a fixation element, such as a spinal rod 12, and a pedicle screw assembly 14 for securing the spinal rod 12 to a vertebra. The pedicle screw assembly 14 comprises a coupling device 15 and a bone screw 18. The coupling device 15 is operable to secure the spinal rod 12 relative to the bone screw 18. The coupling device 15 has an elongate member, such as guide member 16, for guiding the spinal rod 12 onto an open seat of the coupling device 15, such as a saddle body 22. With the spinal rod 12 received on the saddle body 22, a lock device, such as a locking cap 24, is fit onto and guided down along the guide member 16 and engaged with threads 46 of the guide member 16 to fix the spinal rod 12 against the saddle body 22.

6

As can be seen in FIGS. 1 and 2A, the spinal rod 12 rests upon a seating surface 54 of the saddle body 22 generally along an axis 21 that is laterally offset from an axis 23 of the guide member 16. The spinal rod 12 may be slid along and maneuvered around the guide member 16 with any contact between the spinal rod 12 and the guide member 16 providing tactile feedback regarding the position of the spinal rod 12 relative to the saddle body 22. Further, the lateral spacing between the axis 21 and the axis 23 allows the spinal rod 12 to be lowered downwardly along the guide member 16 into position on the saddle body 22 without having to fit the spinal rod 12 through slots or other alignment structures of the pedicle screw assembly 14. In this manner, the spinal rod 12 may be maneuvered around boney structures and tissues adjacent the pedicle screw assembly 14. Once the locking cap 24 has fixed the spinal rod 12 within the saddle body 22, a counter-torque may be applied to the guide member 16 to fracture the guide member 16 at a break-off section 26 so that an upper projection portion 28 of the guide member 16 can be removed.

In one approach, a pair of pedicle screw assemblies 14 are attached to respective vertebral bones via a small incision adjacent each vertebral bone. The spinal rod 12 may be inserted through one of the incisions and passed subcutaneously between the pedicle screw assemblies 14 so as to orient the rod 12 to span the saddle bodies 22 of the pedicle screw assemblies 14. The guide member 16 of each pedicle screw assembly 14 acts as a guidepost for directing movement of the spinal rod 12, with contact between the spinal rod 12 and the guide member 16 indicating that the spinal rod 12 is positioned above the saddle body 22 of the respective pedicle screw assembly 14. Although the guide members 16 partially restrict lateral movement of the spinal rod 12, e.g., the guide members 16A, 16B of FIG. 4 restrict movement of a spinal rod 82 into the page along the Z-axis, the surgeon is able to maneuver the spinal rod 12 using substantially unencumbered movement out of the page along the Z-axis, forward/backward along the X-axis, upward/downward along the Y-axis, and rotationally around the X-, Y-, and Z-axes.

Returning to FIG. 2A, the locking cap 24 has a central throughopening 38 sized to receive shaft 40 of the guide member 16. The locking cap 24 also has tool receiving slot cutouts 42A, 42B extending radially from diametrically opposed sides of the opening 38 for engaging a tool, such as a rod locking sleeve 44, as shown in FIG. 2B. The rod locking sleeve 44 has an opening 39 for receiving the guide member shaft 40 therethrough and prongs 41A, 41B for engaging the cutouts 42A, 42B on the locking cap 24. In alternative embodiments, the prongs 41A, 41B could be replaced by any number of drive interfaces, such as a hex drive, with the locking cap 24 being similarly adapted.

In some instances, the spinal rod 12 may sit proud of the saddle body 22 due to tissues surrounding the pedicle screw 14. To reduce the spinal rod 12 into position on the saddle body 22, the surgeon may use the locking cap 24 and the rod locking sleeve 44 to apply a force to the spinal rod 12 to urge and shift the rod 12 toward the saddle body 22. More specifically, the prongs 41A, 41B are engaged within the cutouts 42A, 42B to releasably connect the rod locking sleeve 44 to the locking cap 24, as shown in FIG. 2B. Next, the connected locking cap 24 and rod locking sleeve 44 are fit onto and moved along the shaft 40 of the guide member 16 until the locking cap 24 contacts the spinal rod 12. Applying downward forces to the rod locking sleeve 44 moves the locking cap 24 and the spinal rod 12 downward until the locking cap 24 reaches the threads 46 of the guide member 16 (see FIG. 2A). The rod locking sleeve 44 is rotated to threadingly

7

engage internal threads 47 of the locking cap 24 with the threads 46 of the guide member 16 and clamp the spinal rod 12 against the saddle body 22. In an alternative configuration, the locking cap 24 may connect to the guide member 16 using a bayonet-style lock or other approach. The rod locking sleeve 44 can be used to impart rotation and/or axial movement to the locking cap 24 in these alternative configurations as well.

The saddle body 22 has a throughbore 48 sized to receive the shaft 40 of the guide member 16, as shown in FIG. 2A. The throughbore 48 and guide member 16 can have a non-rotational mating fit so that the cross-sectional configuration of each is the same and is non-circular. As illustrated, the throughbore 48 and guide member 16 each have a D-shaped cross-sectional configuration with flats 50 and 52, respectively, which are in confronting relation with the shaft 40 extending in the throughbore 48.

With continued reference to FIG. 2A, a seating surface 54 extends along an arm portion 56 of the saddle body 22 and partially around the spinal rod 12. In an alternative configuration, the saddle body 22 comprises a substantially planar surface for receiving the spinal rod 12 that does not extend around the spinal rod 12. The saddle body 22 also has a cup portion 60 that is operable to constrict a flexible socket 62 of the guide member 16 about a head 70 of the bone screw 18 as the saddle body 22 moves axially downward toward a lower end 64 of the guide member 16 and over the flexible socket 62. The flexible socket 62 comprises a plurality of fingers 66 separated by longitudinal slits 68 that resiliently deform according to the axial position of the cup portion 60 on the flexible socket 62. More specifically, when the saddle body 22 is not fully seated on the flexible socket 62, the cup portion 60 constricts the fingers 66 of the flexible socket 62 about the bone screw head 70 but permits relative movement between the flexible socket 62 and the head 70. The engagement between the flexible socket 62 and the bone screw head 70 forms a ball-and-socket connection that permits the guide member 16 to pivot and rotate relative to the bone screw 18. Preferably, there is sufficient friction between the flexible socket 62 and the bone screw head 70 to hold the flexible socket 62 on the head 70 at a set position when the guide member 16 is released. To fix the flexible socket 62 about the bone screw head 70, the locking cap 24 is tightened to shift the cup portion 60 of the saddle body 22 farther axially downward and further constrict the plurality of fingers 66 about the bone screw head 70. The threaded engagement between the locking cap 24 and the threads 46 of the guide member 16 keeps the locking cap 24 in an axial position desired to maintain the fixed relation between the guide member 16 and the bone screw 18, and the respective axes 23 and 25 thereof.

A method of using the spinal fixation system 10 in a minimally invasive surgical approach is illustrated in FIGS. 3A-6. The method utilizes a pair of pedicle screw assemblies 14A, 14B and the components of the assemblies will be identified using reference numbers that are identical to the corresponding components discussed above with a letter A or B added to designate the respective pedicle screw assembly 14A or 14B. Initially, a small incision is made in a patient's skin and other tissues 79 adjacent a first vertebral bone, such as pedicle 80A, and an optional guide wire (not shown) is brought into contact with the first pedicle 80A. If so desired, serial dilators (not shown) are passed over the guide wire and into contact with the first pedicle 80A before an outer sleeve (not shown) is passed over the dilators and secured to the pedicle 80A to form a working channel 81. The outer sleeve may have a non-circular profile in order to accommodate portions of the pedicle screw assembly 14, such as the arm portion 56 of the

8

saddle body 22. The outer sleeve may also have a slot extending along the length of the outer sleeve to pass the spinal rod 82 therethrough. This procedure is repeated for a second level vertebral bone, such as pedicle 80B, to form a working channel 83. The serial dilators and the guide wire may then be removed before drilling and tapping of the pedicle.

Pedicle screw subassemblies 90A, 90B are formed by connecting the flexible socket 62A, 62B of the guide member 16A, 16B to the respective bone screw head 70A, 70B. The pedicle screw subassemblies 90A, 90B may be preassembled or may be assembled during a surgical procedure. Driver tools, such as driver sleeves 92A, 92B, are used to rigidly fix the flexible sockets 62A, 62B on the respective bone screw heads 70A, 70B and drive the subassemblies 90A, 90B into the pedicles 80A, 80B. As shown in FIG. 3B, once the driver sleeve 92 has been moved downwardly over the flexible socket 62 of the guide member 18 in direction 94, a rim 93 of the sleeve 92 is sized to collapse the flexible socket 62 about the bone screw head 70 and fixedly hold the subassembly 90 together. In the illustrated embodiment, the bone screw 18 has a cannula 71 (see FIG. 2A) that may be aligned with a cannula 73 of the guide member 16 and permit the subassembly 90 to be passed along a guide wire (not shown) and into contact with a vertebral bone.

As shown in FIG. 3B, the driver sleeve 92 has a plurality of internal longitudinal fins 95 that extend into the longitudinal slits 68 of the flexible socket 62. The engagement between the internal longitudinal fins 95 of the driver sleeve 92 and the longitudinal slits 68 of the flexible socket 62 permits rotation of the driver sleeve 92 in rotary direction 96 to rotate the subassembly 90. This movement is also shown in FIG. 3A, where rotation of the driver sleeves 92A, 92B in rotary directions 96A, 96B produces concurrent rotation of the pedicle screw subassemblies 90A, 90B and driving of the bone screws 18A, 18B into the respective pedicles 80A, 80B. In an alternative embodiment (not shown), the bone screw head 70 has longitudinal slits aligned with the longitudinal slits 68 of the flexible socket 62 and the internal longitudinal fins 95 of the driver sleeve 92 are sized to engage the slits on the bone screw head 70 as well as the longitudinal slits 68 of the flexible socket 62.

With the pedicle screw subassemblies 90A, 90B secured to the pedicles 80A, 80B, the driver sleeves 92A, 92B are removed and the saddle bodies 22A, 22B are slid downwardly along the guide member shafts 40A, 40B, as shown in FIG. 4A. The saddle bodies 22A, 22B are slid in directions 98A, 98B to seat the cup portions 60A, 60B of the saddle bodies 22A, 22B on the flexible sockets 62A, 62B and to partially constrict the flexible sockets 62A, 62B about the bone screw heads 70A, 70B. The guide members 16A, 16B preferably have sufficient length to extend outward from the respective working channels 81, 83 above the tissue 79 of the patient. In this manner, a surgeon may visually align the spinal rod 82 on one side of the guide members 16A, 16B above the patient's skin before inserting the spinal rod 82 into the working channel 81 adjacent the first pedicle 80A. The guide members 16A, 16B may also have upper threads 100A, 100B for temporarily holding the locking caps 24A, 24B above the saddle bodies 22A, 22B.

A rod inserter 85 is used to guide a distal end 86 of the spinal rod 82 through the working channel 81 adjacent the pedicle 80A at a transverse angle relative to the guide member axis 21A, downward toward the saddle body 22A, beneath tissue 79, and over toward the saddle body 22B in direction 102, as shown in FIG. 4. One rod inserter 85 that may be used to insert the spinal rod 82 is disclosed in U.S. Patent Application Publication No. 2008/0039839 to Songer et al., which

published on Feb. 14, 2008, the entirety of which is hereby incorporated by reference. Although the spinal rod **82** will be moving subcutaneously between the two working channels **81**, **83**, the surgeon can guide the spinal rod **82** into contact with the flats **52A**, **52B** of the guide members **16A**, **16B** and receive tactile feedback that the distal end **86** of the spinal rod **82** is disposed above the saddle body **22A** and a trailing end **84** of the spinal rod **82** is disposed above the saddle body **22B**. Once the spinal rod **82** is properly oriented, the spinal rod **82** is lowered onto the saddle bodies **22A**, **22B** using the guide member shafts **40A**, **40B** as guides. The spinal rod **82** slides along flats **52A**, **52B** of the guide members **16A**, **16B** such that the contact between flats **52A**, **52B** and the spinal rod **82** provides a smooth sliding interface therebetween. In the preferred embodiment, the spinal rod **82** has a round cross-section for producing a line contact with the flats **52A**, **52B**, although other cross-sectional configurations may be used. In another approach, the spinal rod **82** may be inserted generally parallel to the guide member axis **21A** into the working channel **81** before the distal end **86** of the spinal rod **82** is directed toward the saddle body **22B**. Further, the spinal rod **82** may be inserted through a third incision (not shown) into the tissue **79** and along a path transverse to the guide member **16A**.

Once the spinal rod **82** is seated in the saddle bodies **22A**, **22B**, the locking caps **24A**, **24B** can be disengaged from the threads **100A**, **100B**, slid downwardly in directions **98A**, **98B** along the shafts **40A**, **40B**, and tightened onto the respective guide member threads **46** to fix the spinal rod **82** within the saddle bodies **22A**, **22B**. Turning to FIG. **5A**, a pair of rod locking sleeves **44A**, **44B** are operable to disengage the locking caps **24A**, **24B** from the threads **100A**, **100B**, translate the locking caps **24A**, **24B** downward in directions **110A**, **110B**, and to rotate the locking caps **24A**, **24B** in directions **112A**, **112B**, as discussed above with respect to FIG. **2B**. This locks the locking caps **24A**, **24B** onto the spinal rod **82** and clamps the spinal rod **82** against the saddle bodies **22A**, **22B**.

Once the spinal rod **82** has been clamped against the saddle bodies **22A**, **22B**, the rod locking sleeves **44A**, **44B** may be used to stabilize the pedicle screw assemblies **14A**, **14B** while a tool **45** is used to break off the upper projection portions **28A**, **28B**, as shown in FIG. **5B**. The tool **45** comprises a socket **49** having a non-rotational mating fit with the upper projection portions **28A**, **28B** of the guide members **16A**, **16B**. For example, the socket **49** may have a D-shaped cross-sectional configuration with a flat adapted to be in confronting relation with flats **52A**, **52B**. To break off the upper projection portions **28A**, **28B**, the socket **49** is slid downward onto the upper projection portion **28A** and a T-handle **51A** of the rod locking sleeve **44A** is grasped or otherwise secured. Next, a handle **53** of the tool **45** is grasped and rotated in direction **55** to apply a torque to the upper projection portion **28A** while the T-handle **51A** is held stationary. The combination of the torque from the rotating tool **45** and the counter torque from the T-handle **51A** causes the upper projection portion **28A** to shear off at the break-off section **26A** (see FIG. **4**). The upper projection portion **28A** is removed and the tool **45** is used to break off upper projection portion **28B** of the guide member **16B** in a similar manner. In a preferred approach, the torque used to break off the upper projection portions **28A**, **28B** is slightly greater than the torque used to lock the locking caps **24A**, **24B**.

After the upper projection portions **28A**, **28B** have been broken off and removed, the rod locking sleeves **44A**, **44B** are removed from the working channels **81**, **83**. Outer sleeves and/or other tools used to retract the tissue **79** are removed and the incisions are closed, as shown in FIG. **6**. At this point, the pedicle screw subassemblies **14A**, **14B**, the pedicles **80A**,

80B, and the spinal rod **82** are in fixed relation to one another. Although the remaining portions of the guide members **16A**, **16B** are illustrated extending above the locking caps **24A**, **24B**, the break-off sections **26A**, **26B** may be positioned along the guide members **26A**, **26B** such that the remaining portions of the guide members **16A**, **16B** do not extend above the caps **24A**, **24B**.

A spinal fixation system **300** in accordance with another form of the present invention is illustrated in FIGS. **7-10**. The spinal fixation system **300** is similar to the spinal fixation system **10** shown in FIGS. **1-6** but, unlike the spinal fixation system **10**, the spinal fixation system **300** has a saddle body **302** with a cutout **304** in communication with a throughbore **306** for receiving a shaft **308** of a guide member **310**, as shown in FIG. **8**. The cutout **304** allows a distal portion **312** of the guide member **310** to abut a spinal rod **314** when the spinal rod **314** is received against a seating surface **316** of the saddle body **302**. This abutting relation permits a distance **318** between an axis **320** of the spinal rod **314** and an axis **322** of the guide member **310** to be minimized, as shown in FIG. **9**. Because of the proximity between the spinal rod **314** and the guide member **310** within the saddle body **302**, a surgeon may slide the spinal rod **314** downward along the guide member shaft **308** and onto the seating surface **316** in one fluid movement without any lateral movement of the spinal rod **314** away from the guide member shaft **310**. Further, the throughbore **306** opens into an engagement cup **324** (see FIG. **10**) for constricting a flexible socket **326** of the guide member **310** about a spherical head **328** of a bone screw **330**, as shown in FIG. **8**. The engagement cup **324** is similar to the cup portion **60** of the saddle body **22** discussed above. In an alternative embodiments, the bone screw head **328** may have a non-spherical shape, such as cylindrical or elliptical, to provide a desired range of motion of the guide member **310** relative to the bone screw **330**.

A spinal fixation system **500** in accordance with another form of the present invention is shown in FIGS. **11-14**. The spinal fixation system **500** has a ball-and-socket connection between a coupling device **501** and a bone screw **520**. The coupling device **501** has an open seat, such as a pivot body **508**, with a flexible ball **516** that expands within a bone screw head **518**, rather than a guide member flexible socket **62**, **326** that collapses about a spherical bone screw head **70**, **328**, as in the spinal fixation systems **10**, **300** discussed above. The spinal fixation system **500** comprises a spinal rod **502** and a pedicle screw assembly **504** for securing the spinal rod **502** to a vertebra, as shown in FIG. **11**. A locking cap **514** is passed over and along a guide member **506** upstanding from the pivot body **508** until internal threads **568** (see FIG. **13A**) of the locking cap **514** engage threads **570** on a lower portion **522** of the guide member **506**. Returning to FIG. **11**, tightening the locking cap **514** onto the guide member threads **570** causes the flexible ball **516** to expand within the bone screw head **518** and fix the pivot body **508** at a desired angle relative to a shank **524** of the bone screw **520**, as will be discussed in greater detail below.

With reference to FIG. **12**, the locking cap **514** has an upper portion **530** with a plurality of teeth **532** for engaging a rod locking sleeve, e.g., a sleeve similar to the rod locking sleeve **44**. A lower portion **534** of the locking cap **514** may rest against a seat **536** of the pivot body **508** after the locking cap **514** and the pivot body **508** have been passed over the guide member **506** and the locking cap **514** is threaded onto the threads **570** of the guide member **506**. The pivot body **508** has a throughbore **540** and a cutout **542** in communication with the throughbore **540** such that a lower portion **522** of the guide member **506** abuts the spinal rod **502** when the spinal rod **502**

11

rests upon a seating surface 512 of the pivot body 508, in a manner similar to the operation of cutout 304 discussed above with respect to the spinal fixation system 300. The guide member 506 may include a flat 544 that contacts the spinal rod 502 when the spinal rod 502 rests upon the seating surface 512. This contact, in combination with ends 526, 528 of the seat 536, holds the spinal rod 502 against an arm 560 of the pivot body 508. Further, a base 561 of the arm 560 abuts the flat 544 of the guide member 506 to resist rotation of the pivot body 508 about the guide member 506. With continued reference to FIG. 12, the ball 516 of the pivot body 508 comprises a plurality of fingers 546 separated by longitudinal slots 548. The plurality of fingers 546 cover a wedge 550 of the guide member 506 and a tapered annular surface 552 of the wedge 552 when the pivot body 508 is positioned over the distal portion 522 of the guide member 506.

The guide member 506 and the pivot body 508 are connected to the bone screw 520 by passing the ball 516, with the wedge 550 disposed therein, into the socket 554 of the bone screw 520. In one form, passing the ball 516 into a socket 554 comprises deflecting the plurality of fingers 546 inwardly against the guide member 506 to permit the ball 516 to pass into the socket 554. A rim 572 (see FIG. 13A) of the socket 554 may have an inner diameter that is smaller than a maximum outer diameter of the ball 516 such that the rim 572 retains the ball 516 on the wedge 550 and restricts movement of the ball 516 and wedge 550 outward from the socket 554. Alternative embodiments of the bone screw 520 are illustrated in FIGS. 13B and 13C. More specifically, bone screw 520A has a socket 554A with a rim 572A that is tilted relative to a longitudinal axis 571A of the bone screw 520A to provide an additional range of motion of the pivot body 508 in direction 573A from the longitudinal axis 571A, as shown in FIG. 13B. Preferably, the rim 572A has a higher portion 575A that compensates for a lower portion 569A and restricts movement of the ball 516 and the wedge 500 outward from the socket 554A. Another bone screw 520B is shown in FIG. 13C. The bone screw 520B has a socket 554B with a rim 572B, the rim 572B comprising a shallow pocket 577B to provide an increased range of motion of the pivot body 508 in the pocket 577B. The rim 572B has a raised sidewall 579B opposite the pocket 577B to compensate for the reduced engagement between the rim 572B and the pivot body 508 adjacent the pocket 577B. Like the rim 572A, the rim 572B restricts movement of the ball 516 and wedge 550 out of the socket 554B.

With reference to FIGS. 13A and 14, a procedure for fixing the spinal rod 502 to the pedicle screw assembly 504 and fixing the orientation of the pivot body 508 relative to the bone screw 520 is shown. Initially, the spinal rod 502 is received on the seating surface 512 such that the arm 560 extends partially around the spinal rod 502 and a lip 562 restricts movement of the spinal rod 502 from the seating surface 512. In an alternative configuration, the arm 560 defines a generally planar surface or other configuration for receiving the spinal rod 502. The locking cap 514 is passed downward along the guide member 506 and rotated in direction 566 to engage the threads 568 of the locking cap 514 with the threads 570 of the guide member 506 which brings the locking cap 514 into an initial configuration where the lower portion 534 contacts the spinal rod 502. Bringing the locking cap 514 into the initial configuration restricts movement of the spinal rod 502 from the seating surface 512 and maintains the pivot body 508 at an axial position along the guide member 506.

As shown in FIG. 13A, there is initially a gap spacing 577 between an inclined surface 586 on the interior of each of the plurality of fingers 546 and the wedge 550 of the guide mem-

12

ber 506 which permits the fingers 546 to deflect inwardly as the ball 516 is inserted into the socket 554. Further, a gap spacing 576 initially separates a portion of each of the plurality of fingers 546 from an engagement surface 578 of the socket 554 to permit the plurality of fingers 546 to expand radially outward against the socket 554, as will be discussed in greater detail below. Preferably, there is sufficient engagement between the plurality of fingers 546 and the socket 554 so that the pivot body 508 remains stationary when released. To provide smooth movement between the pivot body 508 and the bone screw 520, the wedge 550 may include a rounded tip 580 having a profile complimentary to the engagement surface 578 of the socket 554. In this manner, the guide member 506 may be pivoted and rotated relative to the bone screw 520 as needed to seat the spinal rod 502 on the pivot body 508. Further, the guide member 506 and the bone screw 520 may be aligned to permit passage of a guide wire through respective cannulas 582, 584 of the guide member 506 and bone screw 520.

As shown in FIG. 14, rotating the locking cap 514 in direction 566 to a locked configuration draws the guide member 506 upward in direction 590 relative to the pivot body 508. This movement brings the tapered annular surface 552 of the wedge 550 into contact with the inclined surfaces 586 of the plurality of fingers 546, which expands the fingers 546 radially outward and into engagement with the engagement surface 578 of the socket 554. The plurality of fingers 546 and/or the socket 554 may have a special surface finish, knurling, or coating to improve engagement between the fingers 546 and the socket 554. With the locking cap 514 in the locked configuration, the location of the wedge 550 within the flexible ball 516 is fixed, which keeps the plurality of fingers 546 in an outwardly expanded position and rigidly fixes the ball 516 within the socket 554. In this manner, the pivot body 508 is kept at a desired orientation relative to the bone screw 520. Rotating the locking cap 514 to the locked configuration also clamps the spinal rod 502 between the lower portion 534 of the locking cap 514 and the seating surface 512 of the pivot body 508, thereby fixing the spinal rod 502 within the pedicle screw assembly 504.

With reference to FIGS. 21-25, a spinal fixation system 1010 in accordance with another form of the present invention is disclosed. The spinal fixation system 1010 is substantially similar to the spinal fixation system 500 and FIGS. 23-25 are cross-sectional views substantially similar to FIGS. 13A and 14. One difference between the spinal fixation system 1010 and the spinal fixation system 500 is that the spinal fixation system 1010 has a guide member 1012 with a distal end 1013 comprising a cylindrical step 1014 and a tapered annular surface 1036, as shown in FIG. 21. The step 1014 engages a pivot body 1016 to provide an intermediate stage of fixation between the pivot body 1016 and a socket 1018 of a bone screw 1020. A portion of the pivot body 1016 is removed in FIG. 22 to illustrate an interior recess 1024 of the pivot body 1016. The interior recess 1024 is sized to be complimentary to the step 1014.

As shown in FIGS. 23-25, the spinal fixation system 1010 may be shifted between an initial configuration, an intermediate fixation configuration, and a final locking configuration. Initially, the pivot body 1016 is positioned on the distal end 1013 of the guide member 1012 before a plurality of resilient fingers 1026 of the pivot body 1016 and the distal end 1013 are inserted into a socket 1018 of the bone screw 1020, as shown in FIG. 23. In this initial configuration, the step 1014 and the tapered annular surface 1036 are backed off from the interior recess 1024 and an inclined surface 1038, respectively, of the pivot body 1016. This permits the fingers 1026 to

13

deflect radially inward during insertion of the guide member distal end **1013** and the pivot body fingers **1026** into the socket **1018**. Like the bone screw **520**, the bone screw **1020** may have a rim sized to restrict removal of the guide member distal end **1013** and the pivot body fingers **1026** from the socket **1018**. Once the guide member **1012**, pivot body **1016**, and bone screw **1020** have been connected together, the resulting sub-assembly may be inserted through a working channel and secured to a bone, as discussed above with respect to pedicle screw subassemblies **90A**, **90B** (see FIG. 3A).

With continued reference to FIG. 23, a spinal rod **1022** is seated upon the pivot body **1016** while the spinal fixation system **1010** is in the initial configuration. A locking cap **1028** is slid downward along the guide member **1012** and engaged with threads of the guide member **1012**. The locking cap **1028** is rotated in direction **1030** to draw the locking cap **1028** toward the pivot body **1016** and concurrently draw the guide member **1012** upward in direction **1032** within the pivot body **1016**. This brings the tapered annular surface **1036** of the guide member **1012** into contact with the inclined surface **1038** on the interior of the plurality of fingers **1026** and expands the fingers **1026** radially outward. Drawing the guide member **1012** upward in direction **1032** also positions the step **1014** of the guide member **1012** within the interior recess **1024** of the pivot body **1016**, as shown in FIG. 24. The presence of the guide member step **1014** within the pivot body interior recess **1024** locks the plurality of fingers **1026** in a radially expanded configuration and fixes fingers **1026** against the socket **1018** of the bone screw **1020**. At this point, the spinal fixation system **1010** is in the intermediate fixation configuration. Although the pivot body **1020** is generally fixed relative to the bone screw **1020** via the engagement between the plurality of fingers **1026** and the socket **1018**, the spinal rod **1022** is only loosely captured on the pivot body **1016**.

Continued rotation of the locking cap **1028** in direction **1030** continues to shift the spinal fixation system **1010** to the final locking configuration, as shown in FIG. 25. Specifically, continued rotation of the locking cap **1028** draws the guide member **1012** upward within the pivot body **1016** and clamps locking cap **1028** against the spinal rod **1022**. At this point, the spinal rod **1022** is fixed to the pivot body **1016** and the pivot body **1016** is fixed relative to the bone screw **1020**. In the illustrated approach, the spinal rod **1022** is received on the pivot body **1016** before the locking cap **1028** is used to shift the guide member **1012** to the intermediate fixation configuration. In an alternative approach, the guide member **1012** may be shifted to the intermediate fixation configuration by drawing the guide member **1012** upward within the pivot body **1016** by hand or with a tool (not shown). In this manner, the spinal fixation system **1010** may be shifted to the intermediate fixation configuration after the bone screw **1020** has been driven into a bone but before the spinal rod **1022** has been seated on the pivot body **1016**.

Returning to FIGS. 15 and 16, a spinal fixation system **700** in accordance with another form of the present invention is shown. The spinal fixation system **700** is substantially similar to the spinal fixation system **500**, except that the spinal fixation system **700** has a two-part locking cap **712** instead of the one-part locking cap **514** of spinal fixation system **500**. More specifically, the locking cap **712** has a two-part construction including an upper portion **713** and a lower capture portion **714**, the upper portion **713** being rotatable relative to the lower capture portion **714**. The upper portion **713** has internal threads, e.g., threads **728** in FIG. 17A, to engage a guide member **706**. As the upper portion **713** is advanced downward along the guide member **706**, an arm **726** of the lower capture

14

portion **714** engages the spinal rod **702** and directs the spinal rod **702** into a seating surface (not shown) of an arm **710**. With reference to FIG. 16, the lower capture portion **714** has an opening **716** therethrough and a flat **718** that abuts a flat **720** of the guide member **706** to maintain the lower capture portion **714** in a predetermined orientation relative to the arm **710** as the locking cap **712** travels along the guide member **706**. The lower capture portion **714** may also have a seat **722** that receives the locking cap **712** and a collar **724** that engages complimentary features of the upper portion **713** in a manner that connects the upper portion **713** to the lower capture portion **714** while permitting rotation of the upper portion **713** relative to the lower capture portion **714**.

FIGS. 17A-17D show locking caps **730**, **732**, **734**, and **790** that are similar to the locking cap **712** but illustrate alternative connections between respective upper portions **736**, **738**, **740**, and **792** and lower capture portions **742**, **744**, **746**, and **794**. In FIG. 17A, the upper portion **736** has a neck **748** extending into an opening **750** of the lower capture portion **742**. The neck **748** has a flange **752** extending outwardly into a channel **754** formed in the lower capture portion **742**. The flange **752** and the channel **754** are generally annular in shape about the opening **750** so that with the flange **752** engaged within the channel **754**, the upper portion **736** is rotatable relative to the lower capture portion **742**. The upper portion **736** has an inner wall **756** that defines an axial passage **758** for receiving the guide member **706**. In one approach, the upper portion **730** is connected to the lower capture portion **742** by pressing the neck **748** of the upper portion **736** into the opening **750** of the lower capture portion **742** until the flange **752** snaps into the channel **754**.

FIG. 17B shows a locking cap **732** that is similar to the locking cap **730**, but the upper portion **738** has a neck **760** with a lower flange **762** for retaining the upper portion **738** on the lower capture portion **744**. More specifically, the neck **760** extends through an opening **764** in the lower capture portion **744** to position the flange **762** beneath a body section **766** of the lower capture portion **744**. Because the flange **762** extends below the body section **766**, the pivot body **708** may have an annular cutout on the seat, i.e., seat **536** of the pivot body **508** in FIG. 12, to accommodate the flange **762** and permit the lower capture portion **744** to sit flush against the pivot body **708**.

FIG. 17C shows a locking cap **734** that is similar to the locking cap **730**, but the lower capture portion **746** has an upstanding wall **770** with an inwardly extending flange **772** for retaining the upper portion **740** on the lower capture portion **746**. The flange **772** snaps into a complimentary channel **774** on the upper portion **740**. In this embodiment, an inner wall **776** of the upper portion **740** and an inner wall **778** of the lower capture portion **746** form a passage **780** for receiving the guide member **706**.

FIG. 17D shows a locking cap **790** that is similar to the locking cap **734** except that the lower capture portion **794** has an upstanding wall **796** with an outwardly extending flange **798** that snaps into a complimentary channel **800** on the upper portion **792**. In this embodiment, the upstanding wall **796** forms a portion of a passage **802** for receiving the guide member **706**.

A spinal fixation system **900** in accordance with another aspect of the present invention is illustrated in FIGS. 18-20. The spinal fixation system **900** has a ball-and-socket connection between a yoke **908** and a bone screw **920** for providing a wide range of motion between the yoke **908** and the bone screw **920** during installation of the spinal fixation system **900**. The spinal fixation system **900** comprises a spinal rod **902** and a pedicle screw assembly **904** for securing the spinal

15

rod 902 to a vertebra. The pedicle screw assembly 904 comprises a handle 906 connected to the yoke 908 via a break-off section 910, as shown in FIG. 18. The handle 906 comprises a pair of slots 912, 914 for passing the spinal rod 902 therethrough. The yoke 908 has a ball 916 sized to fit within a socket 918 of the bone screw 920. The connection between the ball 916 and the socket 918 permits the bone screw 920 to be rotated in direction 922 as well as pivoted in a range of motion as shown by arrow 924.

Turning to FIG. 19, the handle 906 has a cannula 930 for passing a locking cap 940 (see FIG. 20) therethrough into connection with threads 942 of the yoke 908. The yoke 908 may also include a cannula 932 that can be aligned with a cannula 934 of the bone screw 920 to accommodate passage of a guide wire. As shown in FIG. 20, the locking cap 940 fixes the spinal rod 902 within the yoke 908. Once the locking cap 940 has been connected to the yoke 908, a torque can be applied to the handle 906 to separate the handle 906 from the yoke 908 at the break-off section 910.

A spinal fixation system 1210 in accordance with another form of the present invention is illustrated in FIG. 26. The spinal fixation system 1210 is substantially similar to the spinal fixation system 700 of FIG. 15, except that the spinal fixation system 1210 has a two-part locking cap 1212 with a lower capture portion 1214 which extends around a spinal rod 1216 a greater amount than the lower capture portion 724 extends around the spinal rod 702. More specifically, the lower capture portion 1214 has an arm 1218 that snaps onto the spinal rod 1216 and extends around an outer surface of the spinal rod 1216. If the locking cap 1212 is used to reduce the spinal rod 1216 into a pivot body 1220 of the spinal fixation system 1210, the arm 1218 may snap onto the spinal rod 1216 and hold the spinal rod 1216 close to a guide member 1222 as the locking cap 1212 and the spinal rod 1216 travel downward along the guide member 1222 toward the pivot body 1220. Another difference between the spinal fixation system 1210 and the spinal fixation system 700 is that the pivot body 1220 has an arm 1224 with a generally planar seating surface 1226 for receiving the spinal rod 1216. When the locking cap 1212 is used to fix the spinal rod 1216 to the pivot body 1220, the arm 1218 clamps the spinal rod 1216 against the seating surface 1226 of the arm 1224.

A pivot body 1410 in accordance with another aspect of the present invention is illustrated in FIG. 27. The pivot body 1410 is substantially similar to the pivot body 1220 of FIG. 26, except that the pivot body 1410 has one or more cylindrical members 1412, 1414 for receiving the spinal rod 1216 rather than the arm 1224. In this manner, the spinal rod 1216 rests upon the convex outer seating surfaces 1413, 1415 of the cylindrical members 1412, 1414. Alternatively, the cylindrical members 1412, 1414 may have planar surfaces for receiving the spinal rod 1216. In other embodiments, the pivot body 1410 may have one or more ledges, arms, or other features for supporting the spinal rod 1216. The one or more features may have a seating surface with protrusions, raised patterns, or a generally roughened surface to engage the spinal rod 1216. If the locking cap 1212 is used to fix the spinal rod 1216 to the pivot body 1410, the arm 1218 of the lower capture portion 1214 captures the spinal rod 1216 against the pivot body 1410. Further, the spinal rod 1216 contacts a flat of the guide member 1222 via a cutout 1418 of the pivot body 1410.

A guide member 1610 in accordance with another aspect of the present invention is illustrated in FIG. 28. The guide member 1610 is substantially similar to the guide member 706 of the spinal fixation system 700 of FIG. 15, except that the guide member 1610 engages a locking cap 1614 (see FIG. 29) in a manner similar to a bayonet-style lock. More specifically,

16

the guide member 1610 has longitudinal channels 1612 on diametrically opposed sides of the guide member 1610. The longitudinal channels 1612 are sized to receive radially projecting tabs 1616, 1618 of an upper portion 1620 of the locking cap 1614. At the end of each of the longitudinal channels 1612 is a circumferentially extending channel 1630 that leads to a vertical locking channel 1632. To engage the locking cap 1614 to the guide member 1610, the tabs 1616, 1618 are aligned with the channels 1612 and the locking cap 1614 is passed downwardly along the guide member 1610 until the tabs 1616, 1618 reach the associated circumferentially extending channel 1630. The upper portion 1620 is rotated clockwise relative to a lower capture portion 1636 of the locking cap 1614 to slide the tabs 1616, 1618 within the associated circumferentially extending channel 1630. The upper portion 1620 is rotated until the tabs 1616, 1618 reach the associated vertical locking channel 1632. In one approach, the lower capture portion 1636 may need to be compressed against the spinal rod 702 and the pivot body 708 to position the tabs 1616, 1618 within the associated circumferentially extending channel 1630. In this manner, rotating the tabs 1616, 1618 into the associated vertical locking channel 1632 allows the lower capture portion 1636, spinal rod 702, and pivot body 708 to bias the upper portion 1620 upward and the tabs 1616, 1618 into an end 1640 of the associated vertical locking channel 1632. At this point, the tabs 1616, 1618 are captured in the associated vertical locking channel 1632 and the locking cap 1614, guide member 1610, spinal rod 702, and pivot body 708 are fixed relative to one another.

It will be understood that various changes in the details, materials, and arrangements of the parts and components that have been described and illustrated in order to explain the nature of the spinal fixation system and method as described herein may be made by those skilled in the art within the principle and scope of this disclosure. Further, it will be readily appreciated by those of skill in the art the apparatuses and methods described herein may be utilized to provide fixation of bones, bone fragments, implants, and other structures besides vertebral bones.

What is claimed is:

1. A spinal fixation system for securing a spinal rod relative to a spinal bone, the system comprising:
 - a bone anchor having a spherical head and a shank depending from the head, the shank extending along a longitudinal axis;
 - a coupling device for being connected to the bone anchor;
 - an elongate guide member of the coupling device having a proximal end portion and a distal end portion and a longitudinal axis extending therebetween, the distal end portion including a flexible socket sized for fitting about the spherical head of the bone anchor for forming a ball and socket joint therewith;
 - an outer surface of the elongate guide member for engaging and guiding the spinal rod;
 - a body of the coupling device having a through opening sized to receive the proximal end portion of the elongate guide member extending therethrough to permit the body to be advanced along the elongate guide member toward the distal end portion thereof;
 - an upwardly open seat of the body laterally offset from the shank longitudinal axis and the elongate guide member outer surface to permit the spinal rod to be slid downward along the outer surface and received on the upwardly open seat laterally offset from the shank longitudinal axis;

17

- a cup portion of the body configured to engage and constrict the flexible socket of the elongate guide member about the spherical bone anchor head for fixing the elongate guide member relative to the bone anchor with shifting of the body cup portion distally over the elongate guide member flexible socket;
- a locking device having a through opening sized to receive the elongate guide member therethrough and permit the locking device to be guidingly advanced downward along the elongate guide member;
- a capture member of the locking device for securing the spinal rod on the body seat; and
- mating surfaces of the elongate guide member and the locking device capture member which have a non-rotatable mating fit therebetween with the elongate guide member extending through the locking device through opening.
2. The spinal fixation system of claim 1 wherein the locking device capture member has a through opening sized to receive the elongate guide member therein and the mating surfaces include an outer surface of the elongate guide member and an inner surface of the capture member which defines at least a portion of the capture member through opening.
3. A spinal fixation system for securing a spinal rod to a spinal bone, the system comprising:
- a bone anchor having a spherical head portion and a shank portion depending from the spherical head portion;
- a body having a seat and a cup portion, the seat configured for receiving a spinal rod;
- an elongate actuator having a proximal portion for upstanding from the body configured to permit the spinal rod to travel therealong toward the body and a distal portion having a plurality of flexible fingers defining a socket for receiving the spherical bone anchor head, the body being shiftable relative to the elongate actuator including the proximal and distal portions thereof from an initial position where the body cup portion is not fully seated on the flexible fingers which permits relative movement between the bone anchor and the body toward a locking position where the body cup portion is fully seated on the flexible fingers and constricts the flexible fingers about the spherical bone anchor head which fixes the bone anchor relative to the body;
- a locking cap configured to be connected to the elongate actuator to engage the spinal rod and secure the spinal rod on the seat of the body; and
- wherein the elongate actuator includes a frangible portion intermediate the proximal and distal portions that is configured to permit the elongate actuator proximal portion to be separated and removed from the distal portion after fixing the bone anchor relative to the body.
4. The spinal fixation system of claim 3 wherein the elongate actuator and the locking cap have rotary locking structures configured to be engaged and shift the locking cap toward the distal portion of the elongate actuator with turning of the locking cap in a locking direction.
5. The spinal fixation system of claim 3 wherein the body has a through opening sized to receive the elongate actuator therein.
6. The spinal fixation system of claim 5 wherein the locking cap includes a through opening sized to receive the elongate actuator therein which is aligned with the through opening of the body when the locking cap is connected to the elongate actuator.
7. The spinal fixation system of claim 3 wherein the shank portion of the bone anchor extends along a longitudinal axis thereof and the seat of the body is laterally offset from the

18

- shank portion longitudinal axis to permit the spinal rod to travel along the elongate actuator proximal portion and be received on the seat laterally offset from the shank portion longitudinal axis.
8. A spinal fixation system for securing a spinal rod relative to a spinal bone, the system comprising:
- a bone anchor having a head with a socket and a shank depending from the head, the shank extending along a longitudinal axis;
- a coupling device for being connected to the bone anchor; an elongate guide member of the coupling device having a longitudinal axis;
- an outer surface of the elongate guide member for engaging and guiding the spinal rod;
- an upwardly open seat of the coupling device laterally offset from the shank longitudinal axis and the elongate guide member outer surface to permit the spinal rod to be slid downward along the outer surface and received on the upwardly open seat laterally offset from the shank longitudinal axis; and
- a flexible ball portion of the coupling device that is integral with the upwardly open seat of the coupling device so that the flexible ball portion and the upwardly open seat have a one-piece construction with the flexible ball portion thereof being sized and configured to be received in the socket of the bone anchor head to form a ball and socket joint therewith;
- wherein the coupling device includes a one-piece body that includes the seat and the flexible ball portion;
- the body and elongate guide member include primary engagement surfaces arranged and configured such that shifting the elongate guide member from an initial position toward a locking position brings the primary engagement surfaces together which deflects the flexible ball portion outwardly against an inner surface of the bone anchor socket; and
- wherein the body and the elongate guide member include secondary engagement surfaces adjacent the primary engagement surfaces that are configured such that shifting the elongate guide member to an intermediate position between the initial and locking positions brings the secondary engagement surfaces together and produces an initial outward deflection of the flexible ball portion.
9. A spinal fixation system for securing a spinal rod to a spinal bone, the system comprising:
- a bone anchor having a spherical head portion and a shank portion depending from the spherical head portion;
- a body having a seat and a cup portion, the seat configured for receiving a spinal rod;
- an elongate actuator having a proximal portion for upstanding from the body configured to permit the spinal rod to travel therealong toward the body and a distal portion having a plurality of flexible fingers defining a socket for receiving the spherical bone anchor head, the body being shiftable relative to the elongate actuator including the proximal and distal portions thereof from an initial position where the body cup portion is not fully seated on the flexible fingers which permits relative movement between the bone anchor and the body toward a locking position where the body cup portion is fully seated on the flexible fingers and constricts the flexible fingers about the spherical bone anchor head which fixes the bone anchor relative to the body; and
- a locking cap configured to be connected to the elongate actuator to engage the spinal rod and secure the spinal rod on the seat of the body;

19

wherein the body has a through opening sized to receive the elongate actuator therein; and
 wherein the body includes an arm that includes at least a portion of the seat with the arm extending laterally from the body through opening such that the spinal rod is positioned laterally relative to the elongate actuator on the arm.

10. A spinal fixation system for securing a spinal rod relative to a spinal bone, the system comprising:

a bone anchor having a spherical head and a shank depending from the head, the shank extending along a longitudinal axis;

a coupling device for being connected to the bone anchor; an elongate guide member of the coupling device having a proximal end portion and a distal end portion and a longitudinal axis extending therebetween, the distal end portion including a flexible socket sized for fitting about the spherical head of the bone anchor for forming a ball and socket joint therewith;

an outer surface of the elongate guide member for engaging and guiding the spinal rod;

a body of the coupling device having a through opening sized to receive the proximal end portion of the elongate guide member extending therethrough to permit the body to be advanced along the elongate guide member toward the distal end portion thereof;

an upwardly open seat of the body laterally offset from the shank longitudinal axis and the elongate guide member outer surface to permit the spinal rod to be slid downward along the outer surface and received on the upwardly open seat laterally offset from the shank longitudinal axis;

a cup portion of the body configured to engage and constrict the flexible socket of the elongate guide member

20

about the spherical bone anchor head for fixing the elongate guide member relative to the bone anchor with shifting of the body cup portion distally over the elongate guide member flexible socket; and

wherein the upwardly open seat of the body extends about a seat axis along which the spinal rod is oriented with the spinal rod received on the upwardly open seat and the seat axis is laterally offset from the bone anchor shank longitudinal axis.

11. The spinal fixation system of claim **10** further comprising a locking device having a clamping portion configured to engage the spinal rod and an opening sized to receive the elongate guide member therethrough to allow the locking device to be advanced onto and downward along the elongate guide member to clamp the spinal rod against the body seat.

12. The spinal fixation system of claim **11** wherein the locking device has an inner portion configured to be connected to the elongate guide member and the clamping portion includes an outer clamping member extending laterally from the inner portion to clamp the spinal rod against the body seat.

13. The spinal fixation system of claim **10** wherein the body includes a lateral opening to the seat in communication with the body through opening to minimize the lateral distance between the elongate guide member and the spinal rod with the spinal rod received on the seat.

14. The spinal fixation system of claim **10** wherein the elongate guide member flexible socket and the bone anchor spherical head portion are configured to permit the elongate guide member longitudinal axis and the bone anchor shank longitudinal axis to be coaxially aligned with the flexible socket connected to the spherical head portion.

* * * * *